EXHIBIT "A"

DEPOSITION SUBJECT MATTER

Pursuant to Rule 30(b)(6), the deponent(s) must have knowledge and shall be able to testify concerning the following subject matters:

1. All complaints and reports received by Defendants during the Relevant Time Period for TVT reporting particles or foreign material in the product or packaging.

2. All communication sent by Defendants to healthcare providers or received by Defendants from healthcare providers during the Relevant Time Period regarding reports of particles or foreign material in TVT packaging or product, including any communication indicating whether or not TVT products were safe to use despite particles or foreign material being present in the product or packaging.

3. Person Most Knowledgeable regarding e-mail and attached photographs "Product Complaint CC1007005-Taiwan" (ETH.MESH.13204508-ETH.MESH.13204521) attached as Exhibit A-1.

4. Any data relied upon to support the conclusions that the tiny mesh pieces described in Exhibit A-1 are not normal, and that Ethicon does not recommend using the TVT-O product described in Exhibit A-1, including but not limited to: any literature, complaint review, or other analyses performed by Defendants or relied upon by Defendants to support those conclusions.

5. Person Most Knowledgeable regarding e-mail and attached PowerPoint Presentation "Particles in TVTO Blisters" (ETH.MESH.04101823-04101824) attached as Exhibit A-2.

6. Any analyses performed by Defendants to determine the costs involved with any potential action to recall or reclaim any TVT lot number(s), including any analyses performed by Defendants analyzing lost sales or lost goodwill as a result of any potential recall.

7. Any operating procedures, standards, worksheets, or specifications used by Defendants during the Relevant Time Period for acceptance or rejection of TVT product based on particles or foreign material in the product or packaging, including but not limited to: TM403-166, EMQD10, VSE0007, C/L-E0038, and TAPPI 213/T437.

8. Any changes during the Relevant Time Period to operating procedures, standards, worksheets, or specifications used by Defendants for acceptance or rejection of TVT product based on particles or foreign material in the product or packaging, including but not limited to: TM403-166, EMQD10, VSE0007, C/L-E0038, and TAPPI 213/T437.

9. Any medical analyses performed by Defendants or medical conclusions reached by Defendants regarding the appropriate operating procedures, standards, or specifications for acceptance or rejection of TVT product based on particles or foreign material in the product or packaging.

10. Person Most Knowledgeable regarding "Memo re TVT-O Particles" (ETH.MESH.04101014-04101015) attached as Exhibit A-3.

11. Any data relied upon by Defendants to support the conclusion that the presence of the tiny tape fragments in TVT product packages described in Exhibit A-3 is not expected to change the product safety profile of the TVT, including but not limited to: any literature, complaint review, medical analyses, or other analyses performed by Defendants or relied upon by Defendants to support that conclusion.

12. Any data relied upon by Defendants to support the conclusion that the possibility for the tiny tape fragments to cause an adverse consequence to the patient is remote as described in Exhibit A-3, including but not limited to: any literature, complaint review, medical analyses, or other analyses performed by Defendants or relied upon by Defendants to support that conclusion.

13. Person Most Knowledgeable regarding e-mail chain "FW: Product Complaint CC1007005-Taiwan" (ETH.MESH.01745568-01745572) attached as exhibit A-4.

14. Any official letter, draft letter, or other correspondence to physicians, hospitals, or regulatory authorities to explain that the tiny pieces in TVT packaging do not pose a health risk and are safe to use as described in exhibit A-4.

15. Person Most Knowledgeable regarding returned TVT-O products described in e-mail chain "FW: Product Complaint CC1007047&CC1007048-Taiwan (TVTO:810081)" attached as exhibit A-5, (ETH.MESH.13206130-13206134) including but not limited to: any testing or analyses that was done on those products, any photographs or those products, and current location of those products, including date of disposal and reason for disposal, if applicable.

16. Person Most Knowledgeable regarding e-mail and attached PowerPoint "Particles in Production" (ETH.MESH.13907354-13907355) attached as exhibit A-6.

17. Any analyses or conclusions reached by Defendants as to the cause of the increase in Prolift, TVT, TVT-O, and P1990X products that were rejected due to particles or foreign matter in March of 2010.

18. Any corrective actions performed by Defendants to address the increase in Prolift, TVT, TVT-O, and P1990X products that were rejected due to particles or foreign matter in March of 2010.

19. Person Most Knowledgeable regarding "Ethicon's Procedure for Complaint Management PR-000118" (ETH.MESH.08462125-08462148) attached as exhibit A-7, including, but not limited to the applicability of litigation holds to the portion of the policy which provides that returned complaint samples not related to reportable adverse events may be discarded upon completion of the investigation.

20. The date(s) when Defendants began to retain rather than discard returned TVT complaint samples in response to any litigation hold(s).

21. All returned TVT complaint samples currently in the possession of Defendants, including date of receipt, reason for return, lot number, and any analyses or testing performed on those samples.

22. The operating procedures, schedule, and records maintained by Defendants in maintenance and cleaning of any equipment used to cut the TVT mesh during the Relevant Time Period, including the location and storage of records.

23. The operating procedures, schedule, and records maintained by Defendants in the maintenance and cleaning of any manufacturing areas where the TVT mesh is cut, packaged, or sterilized during the Relevant Time Period, including the location and storage of records.

EXHIBIT A-1

From: Chen, Kathie [MEDTW] <KCHEN6@ITS.JNJ.COM>
Sent: Mon, 05 Jul 2010 10:57:10 GMT
To: Kyle, Darlene Jane [ETHUS] <DKyle5@its.jnj.com>
CC: Heramza, Céline [JNJCH] <cheramza@its.jnj.com>
Subject: RE: Product Complaint CC1007005-Taiwan

Dear Darlene,
Thanks a lot for your mail.
Attached please find the MD&D form for this complaint.
Because all these four TVTO are complained from same hospital, we put these 4 cases into one complaint.
Please provide us the tracking number and we will return the products.

Thanks again,
Kathie

From: Kyle, Darlene Jane [ETHUS]
Sent: Saturday, July 03, 2010 1:20 AM
To: Chen, Kathie [MEDTW]
Subject: RE: Queries about TVT Obturator-Taiwan

Kathie,

No this is not normal nor do we recommend using the product. Please complete complaint forms for each and send for entry into the complaint handling system. Since the devices were not used they can be sent directly her once a complaint number has been assigned.

Thank you.

Darlene

From: Chen, Kathie [MEDTW]
Sent: Friday, July 02, 2010 6:53 AM
To: Kyle, Darlene Jane [ETHUS]
Subject: RE: Queries about TVT Obturator-Taiwan

Dear Darlene,
Today we received another 3 cases the same as yesterday. (Our customers are so angry about this)
I took another pictures for your reference.
<< File: 20100702.zip >>
Please let us know whether it's safe to use.

If this is the normal and safe condition, could you please provide us the formal declaration letter because we need to reply to our customer by next Monday.

Could you please forward this on, if you are not the appropriate person to deal with.

Thanks a lot for your help in advance.

Best Regards,
Kathie

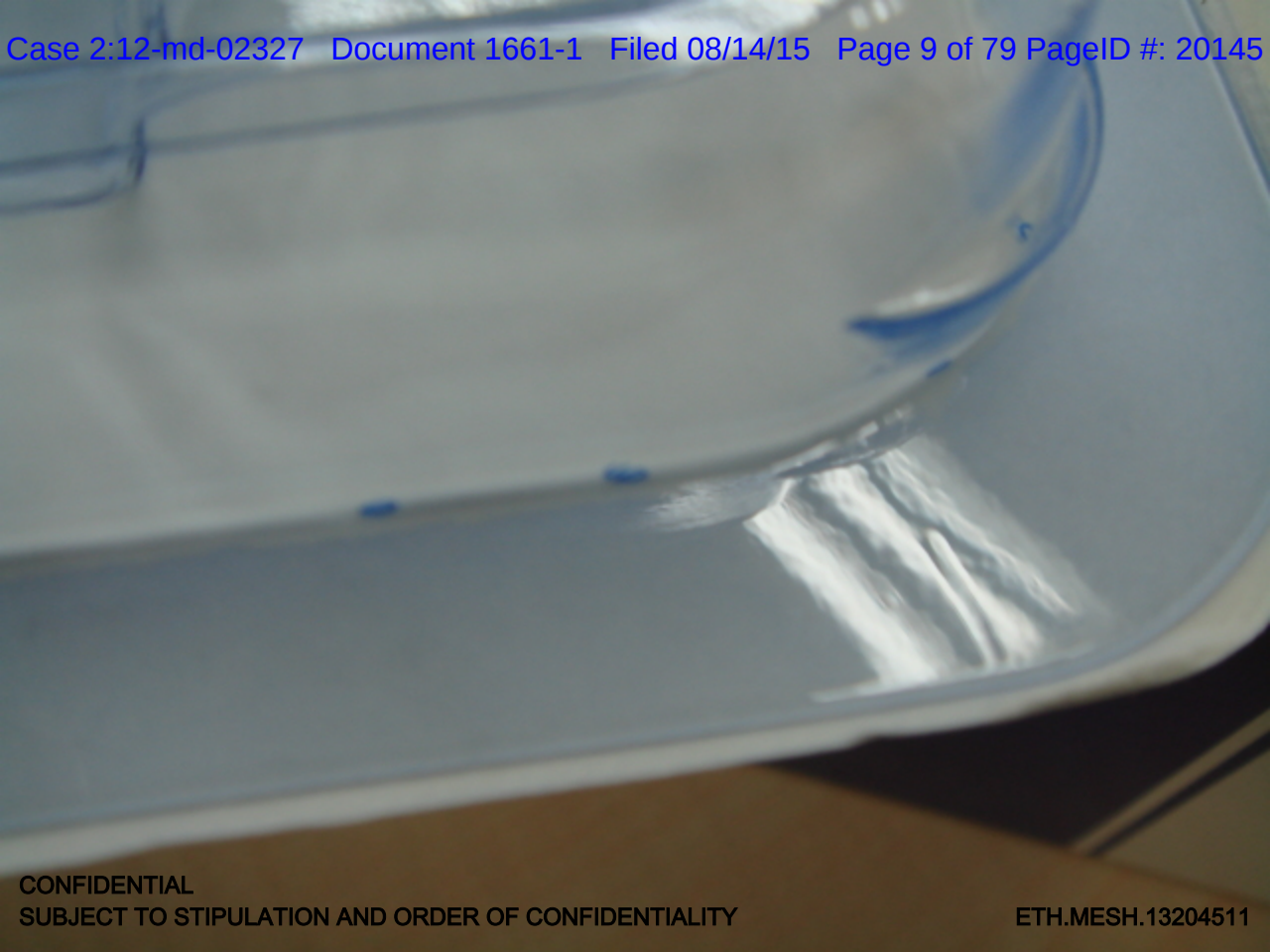
From: Chen, Kathie [MEDTW]
Sent: Thursday, July 01, 2010 6:58 PM
To: Kyle, Darlene Jane [ETHUS]
Subject: Queries about TVT Obturator-Taiwan

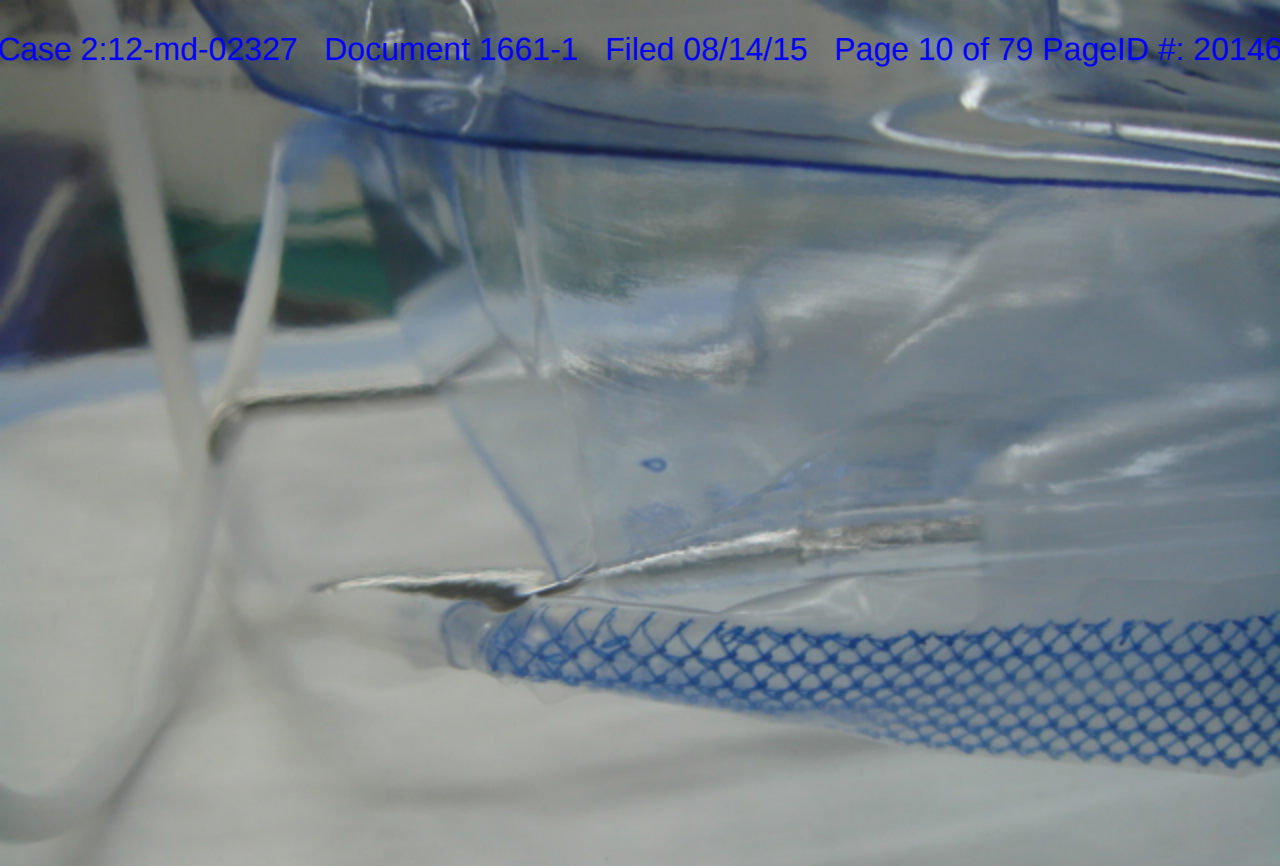
Dear Darlene,
Good day! I have some quality queries about the product TVT Obturator System, could you please answer it for me?
Today our customer found some tiny mesh pieces (about 2 mm) in the unopened tyvek box.
So they refused to accept the product TVTO (Code:810081).
Could you please let me know why did these tiny mesh pieces fall within the sterile package?
Is this product with tiny mesh pieces safe to be used?

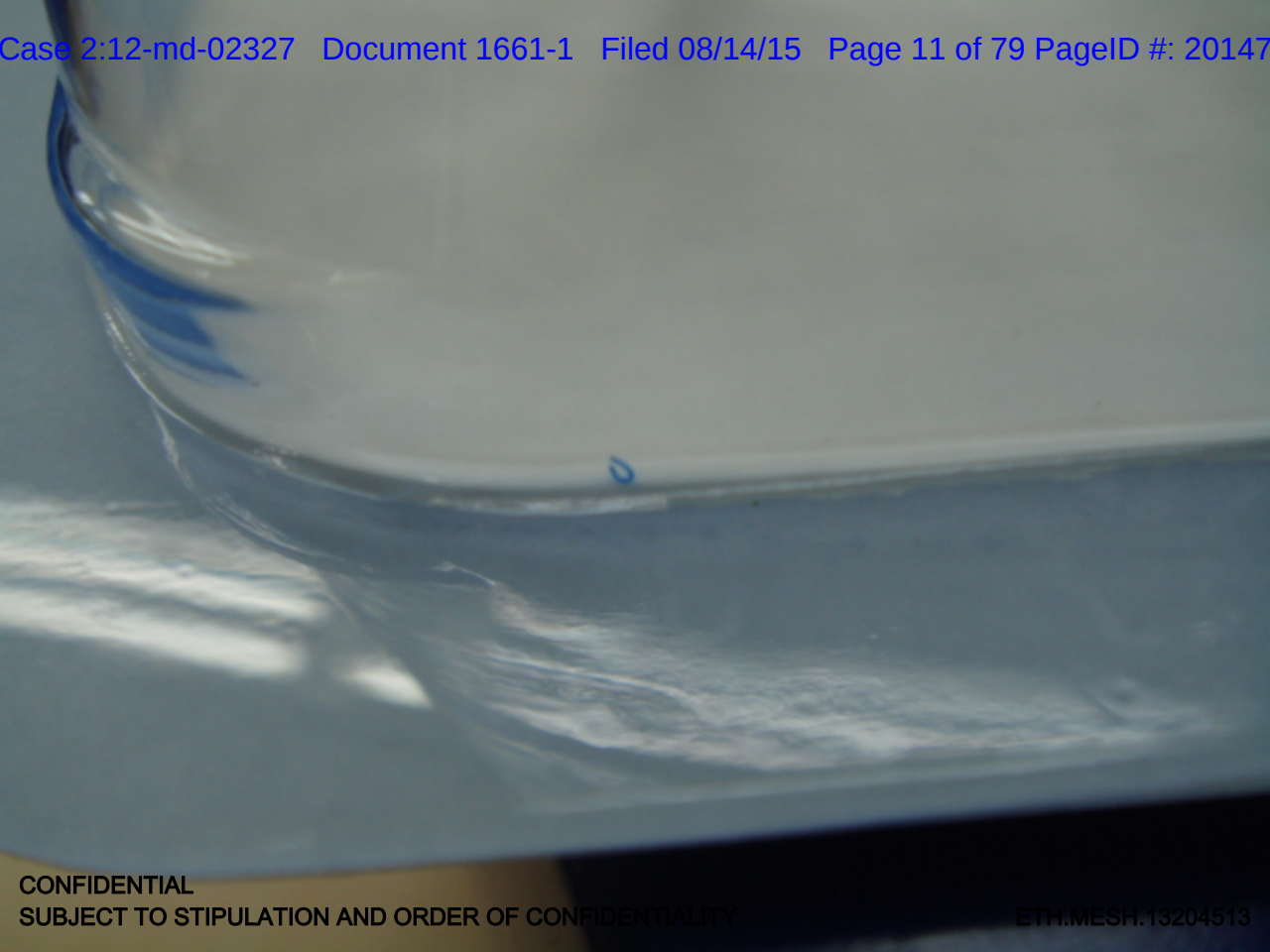
Attached please find the several pictures for this issue.
<< File: TVTO.zip >>
It's greatly appreciated for your reply, and thank you so much for your kind help.

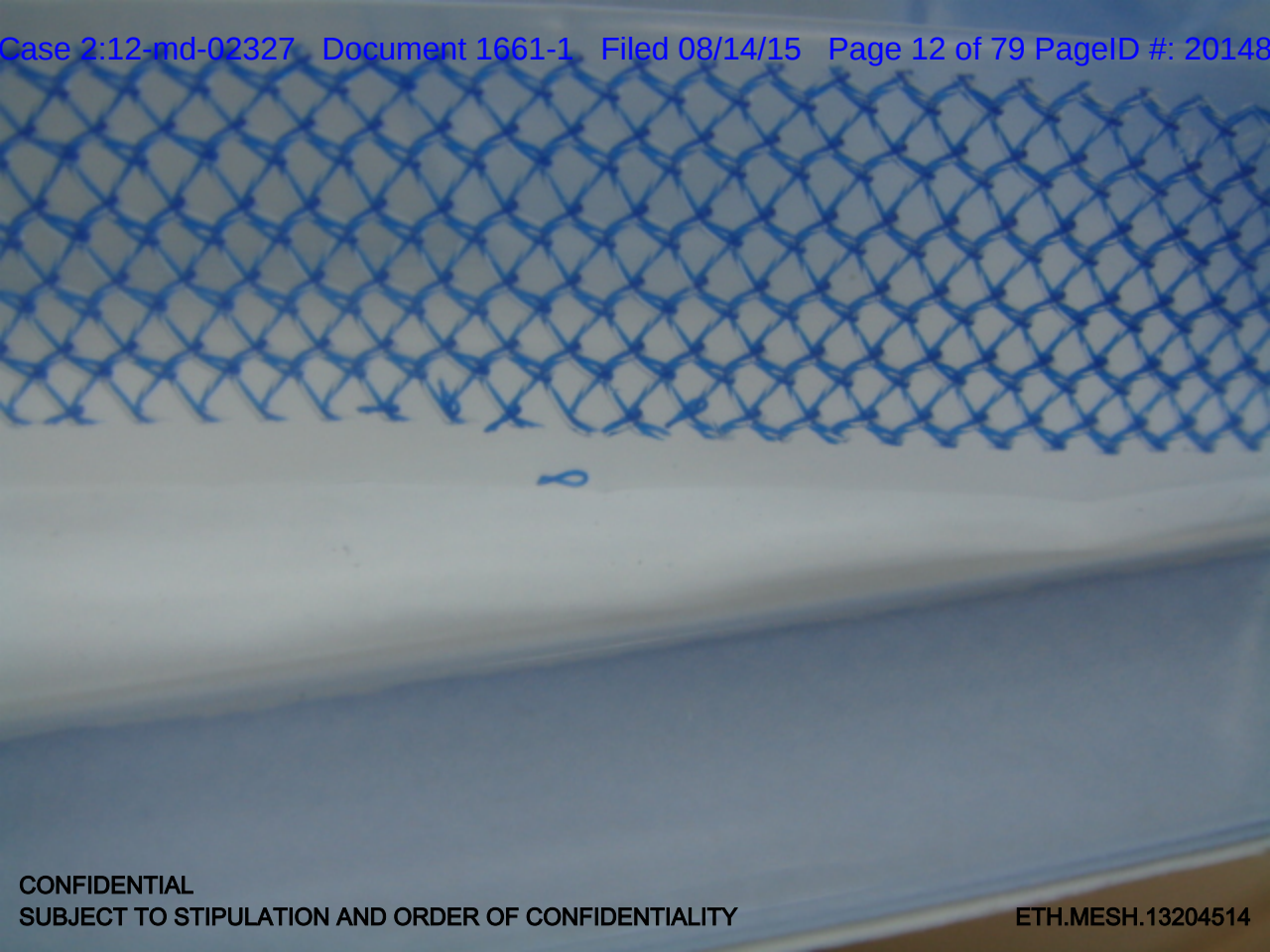
Many thanks,
Kathie

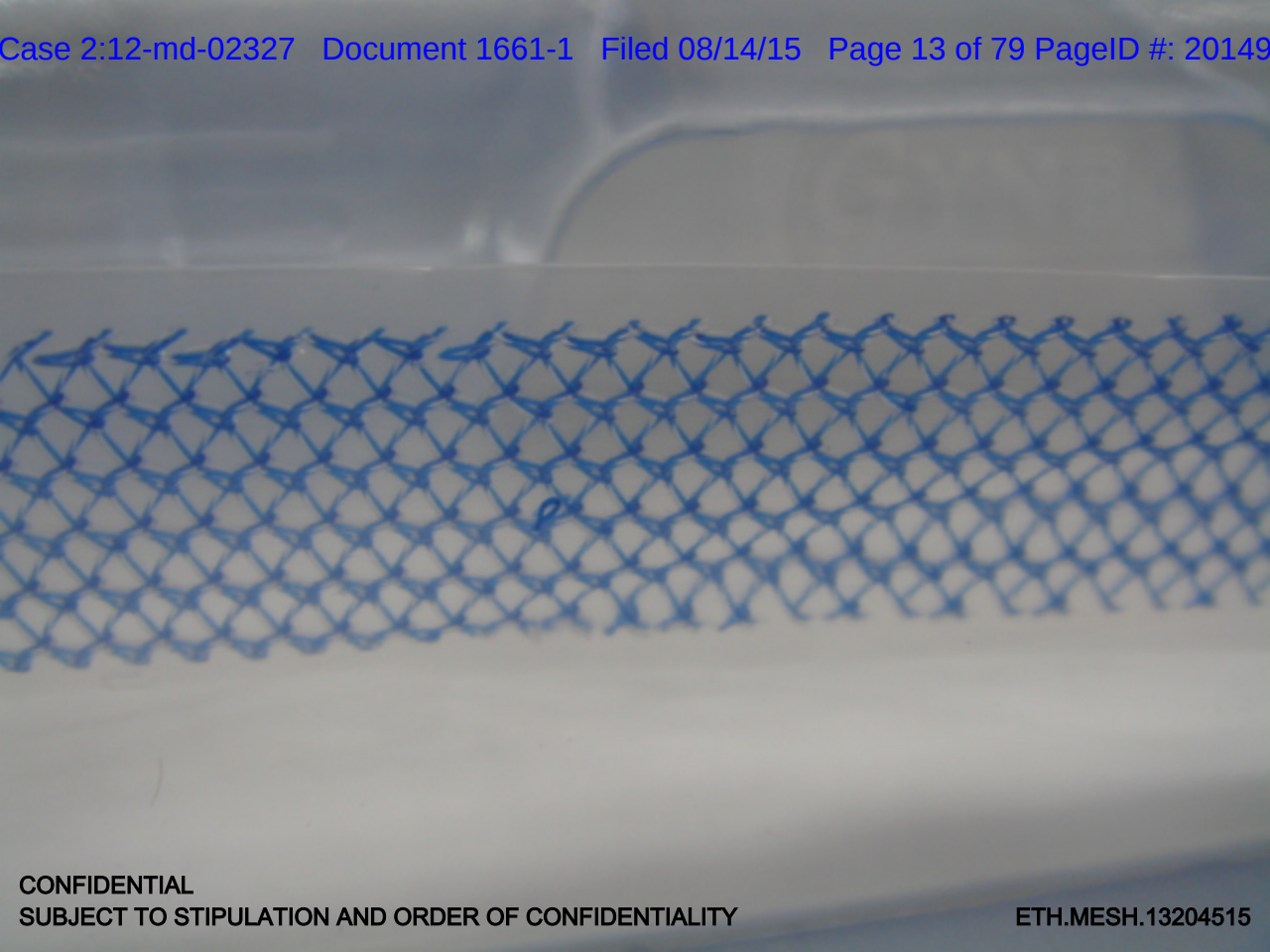
Johnson &Johnson Medical Taiwan
Professional Affairs & Corporate Communications Dept.
6F. 319, Sec.2, Tun Hwa S. Rd, Taipei 106, Taiwan
Tel: +886-2-23764849/ FAX: +886-2-27386380

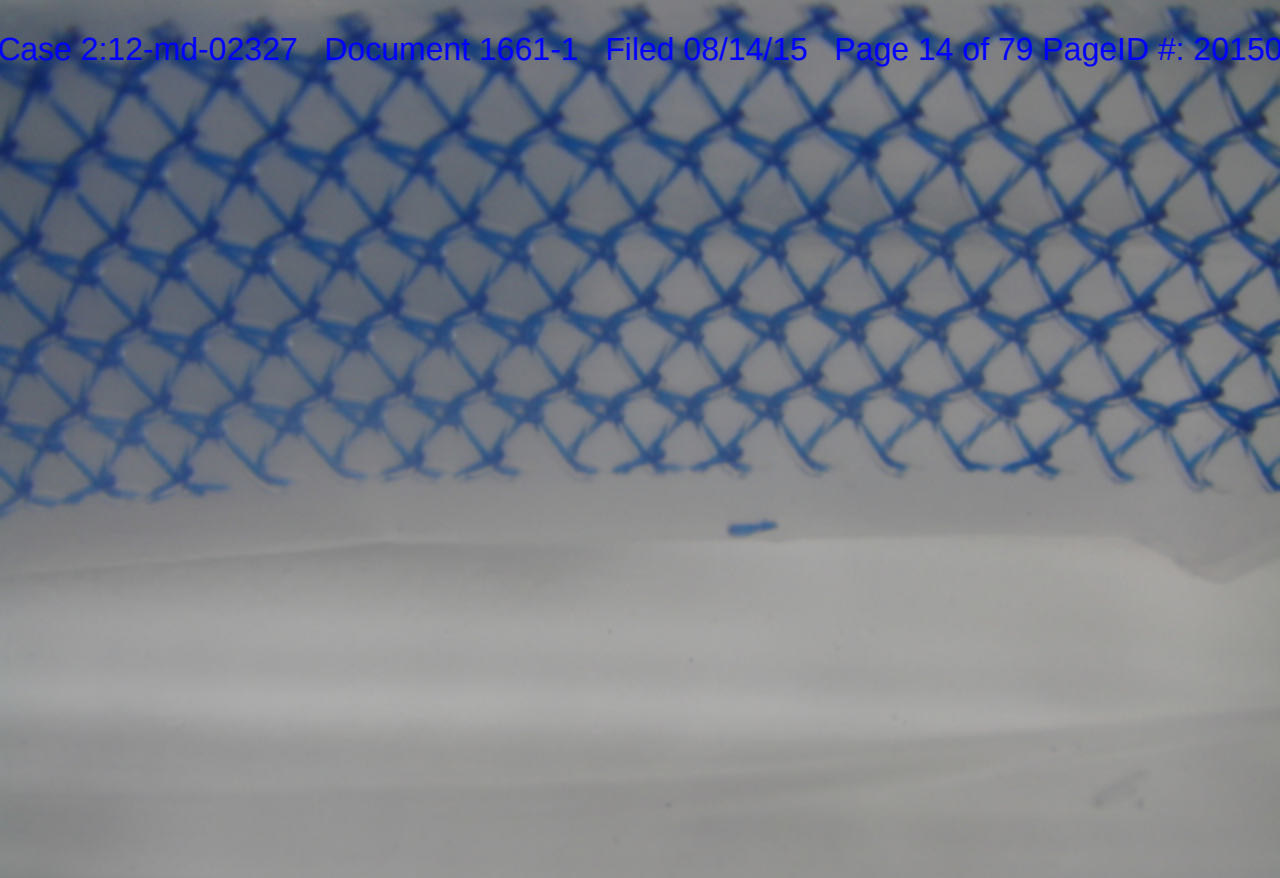


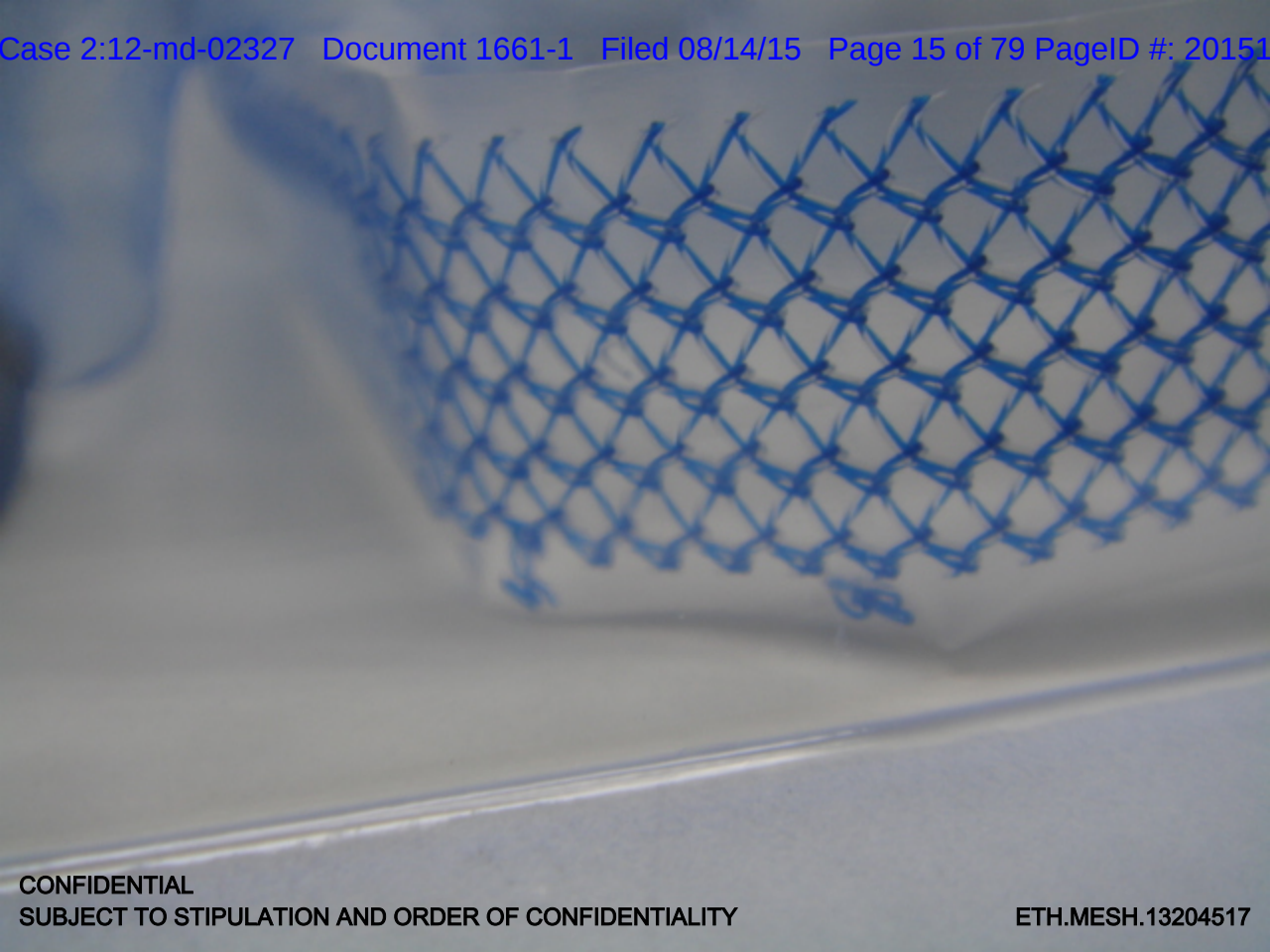


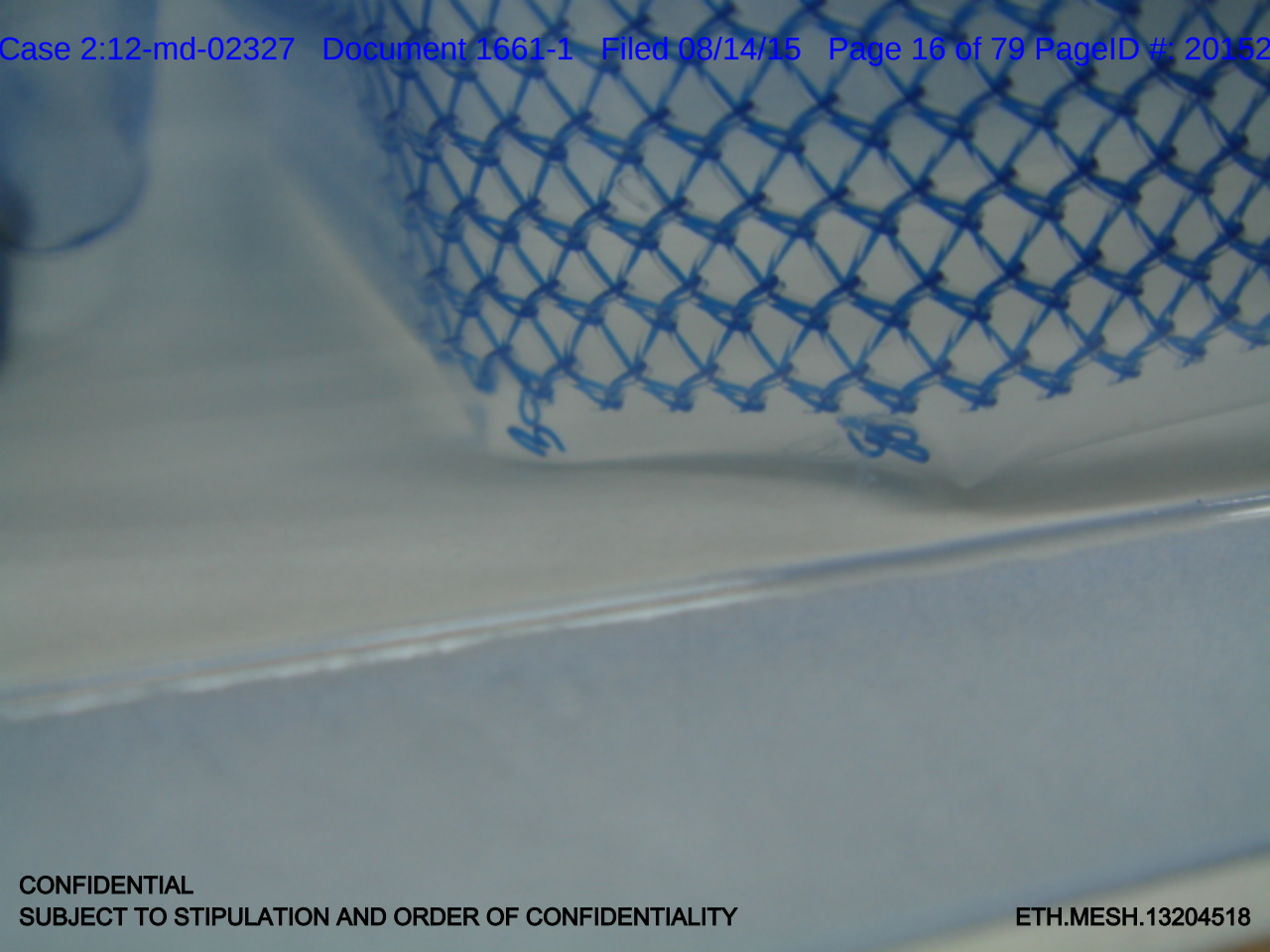


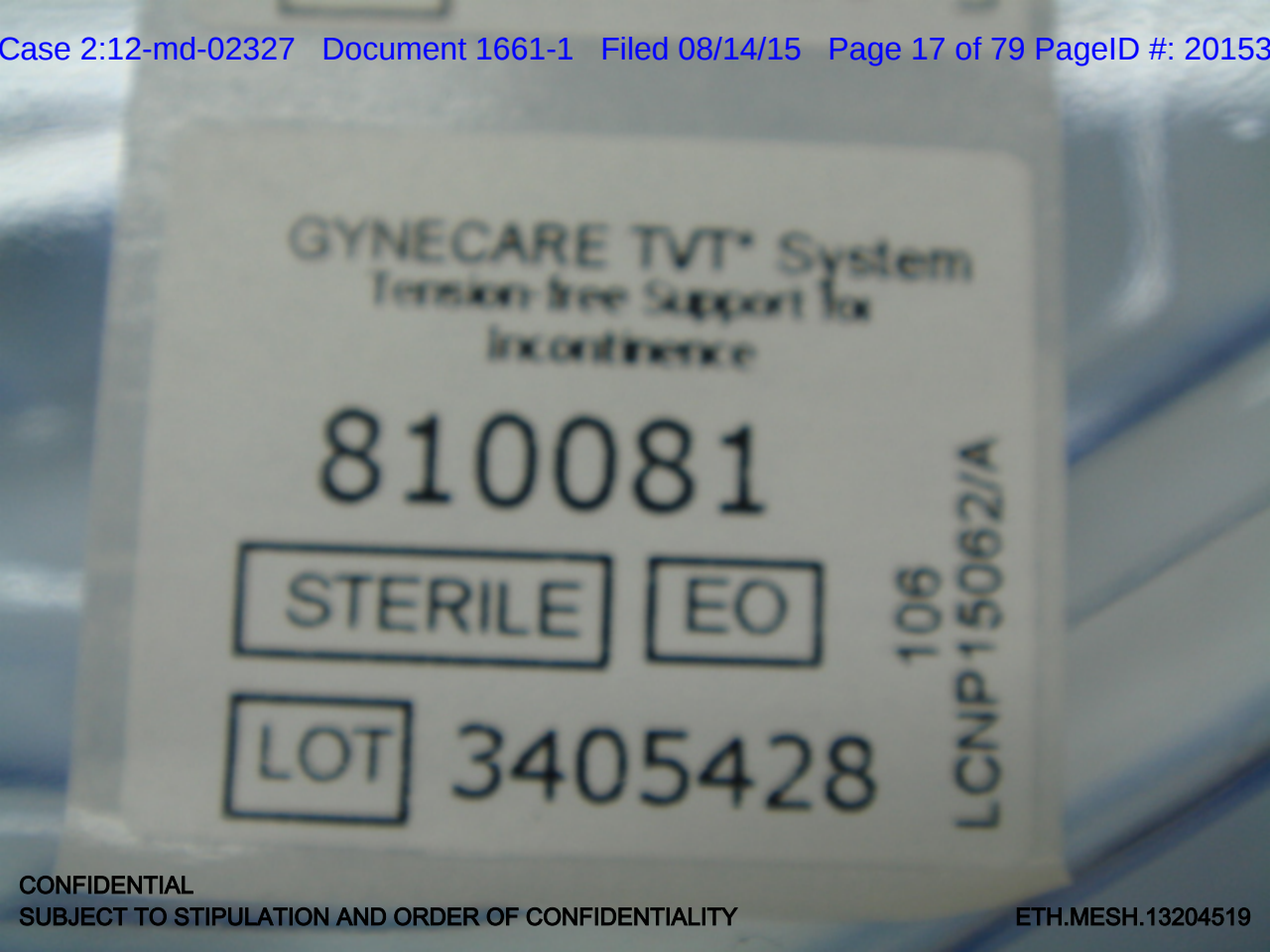












MD&D Complaint Form

Affiliate Information

Complaint ID	CC1007005
MFG Complaint ID	
Company	4890 - Johnson & Johnson Medical Taiwan
Country	Taiwan
Contact Name	Kathie Chen
Fax Number	+886 2 27386380
Phone Number	+886 2 23764849
Affiliate Email Address	kchen6@its.jnj.com

Franchise Information

Franchise ID	OTHER
Company Name:	Ethicon Sarl
Country:	Switzerland
Address:	Puits-Godet 20, CH-2000 Neuchâtel, Switzerland
Fax:	+41 32 934 8610
Email:	cheramza@its.jnj.com

Complaint Details

1010	Did the Affiliate report the event to the local Health Authorities?	Affiliate-No
1080	Was the Complaint Submitted Before by the Affiliate?	No
1009	Sales Rep Name	Odey Kuo
	Complaint Create Date:	5-JUL-2010

Reporter Information

1113	Was this product involved in a clinical trial or post-market study?	No
1017	Initial Reporter Type	Hospital
1025	Reporter Name (The name of the person who first identified & reported the event):	Shu-Xian Chen
1027	Facility Name	Chang Gung Memorial Hospital (Linkou)
1030	Reporter City	Tao Yuan
1032	Reporter Country	Taiwan
1034	Reporter Telephone Number	+886 3 3281200 ext. 2380

Product Problem Information

1035	Is it a Potential Adverse Event?	No
1036	Event or Product Problem Outcome	None Reported
1095	Has the surgeon or doctor provided a medical rationale that indicates the use of the product is in no way related to the reported event?:	Yes
1046	Date the event, if different from date of procedure/surgery:	1-JUL-2010
1048	On what date was the event first reported to a J&J Representative?	1-JUL-2010

Product Information

MD&D Complaint Form

1076 Product Description	1052 Product Catalog Number	1053 Product Serial Number/Batch Number	1054 Product Lot Number	1055 Product Qty Involved	1057 Product Qty Returned	1059 Product Status
TVT Obturator System	810081	NA	3413118	1 Case	1 Case	Component Return
TVT Obturator System	810081	NA	3398077	1 Case	1 Case	Component Return
TVT Obturator System	810081	NA	3405428	2 Case	2 Case	Component Return

Device Information

1051	Operator Type	Health Professional
1061	Is this report related to a:	Single Use Device
1065	When did the device problem occur?	Before used on patient
1074	Is this report related to a piece of capital equipment?	No
1077	Did the event occur during a procedure/surgery?	No
1049	Describe Event	Some tiny mesh pieces (about 2 mm) within the unopened package.

Confidential - Not for Distribution Outside the Company

EXHIBIT A-2

From: Armstrong, Shalot [JNJCH] <sarmstr2@ITS.JNJ.com>

Sent: Wed, 01 Sep 2010 14:57:06 GMT

To: Heron, Claire [JNJCH] <CHERON@its.jnj.com>; Brennan, Carolyn [ETHUS] <CBrennan@its.jnj.com>; Chen, Meng [ETHUS] <MChen28@its.jnj.com>; Lisa, Bryan [ETHUS] <BLisa@its.jnj.com>; Brunner, Neal T. [ETHUS] <NBrunner@its.jnj.com>; Day, Melissa [ETHUS] <MDay4@its.jnj.com>; Robinson, David [ETHUS] <DRobin11@its.jnj.com>; Schmitt, Konrad [MEDDE] <KSchmit1@its.jnj.com>; Lugo-Ponce, Carlos E. [ETHUS] <CLugo3@its.jnj.com>; Kyle, Darlene Jane [ETHUS] <DKyle5@its.jnj.com>; Poulot, Stéphane [JNJCH] <spoulot@its.jnj.com>; Hostache, Karine [JNJCH] <khostach@its.jnj.com>

Subject: Product Complaint CC1007005-Taiwan

Here is the presentation for today's meeting

Best Regards,

Shalot Armstrong, CQE
Manager, Quality Systems and Compliance
ETHICON a *Johnson & Johnson* company
Puits-Godet 20 - 2000 Neuchâtel - Switzerland
voice mail: +41 32 934 9695
cell phone +41 79 751 8774 or 908-745-9876(US)
e-mail: SArmstr2@its.jnj.com

Sometimes in the winds of change we find our true direction - unknown

Placeholder

Document produced in native format

NEUCHATEL

Particles in TVTO Blisters

ETHICON
a Johnson & Johnson company

TVTO Complaints

Since July 2010, 6 complaints have been recorded for the following issue : Foreign Matter in TVTO blisters.

Date demande	Product Code	Subject	# Complaint	# Dossier	Country
06.07.2010	810081	Foreign Matter	10100122655	3413118	Taiwan
06.07.2010	810081	Foreign Matter	10100122655	3398077	Taiwan
06.07.2010	810081	Foreign Matter	10100122655	3405428	Taiwan
02.08.2010	810081	Foreign Matter	10100124603	3413119	Taiwan
02.08.2010	810081	Foreign Matter	10100124604	3413121	Taiwan
02.08.2010	810081	Foreign Matter	10100124606	3389753	Taiwan
02.08.2010	810081	Foreign Matter	10100124625	3422101	Taiwan
02.08.2010	810081	Foreign Matter	10100124640	3412830	South Africa

- All complaints listed above are linked to TVT-O Manual Code : 810081
- 5 complaints from Taiwan and 1 from South Africa–> 2 different Surgeons raised the complaints

Products Complaint Investigation

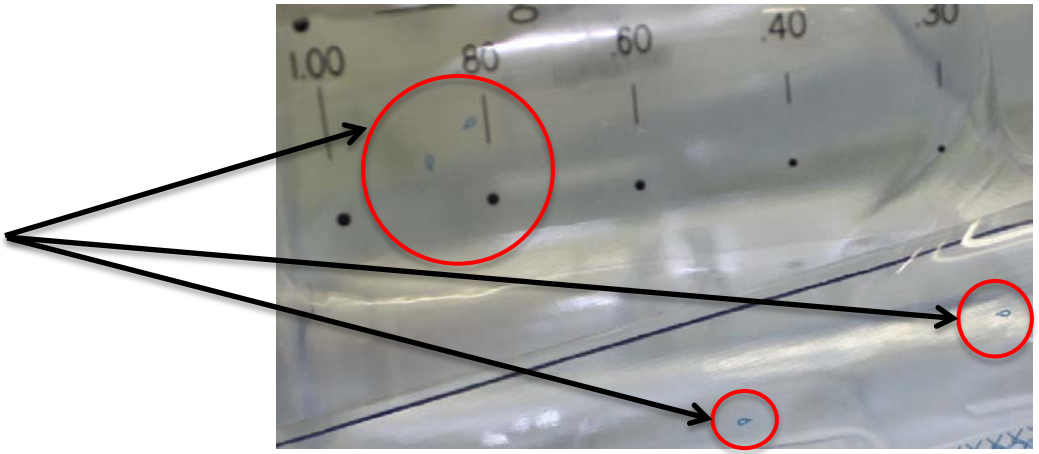
-> Only Blue and White particles of Prolene mesh have been detected inside the blisters.

-> The presence of Prolene particles in the blister is common for a manual code compared to laser code.

-> The size of particles is equal or inferior to 3mm

=> Conform to product specifications

Particles of Mesh



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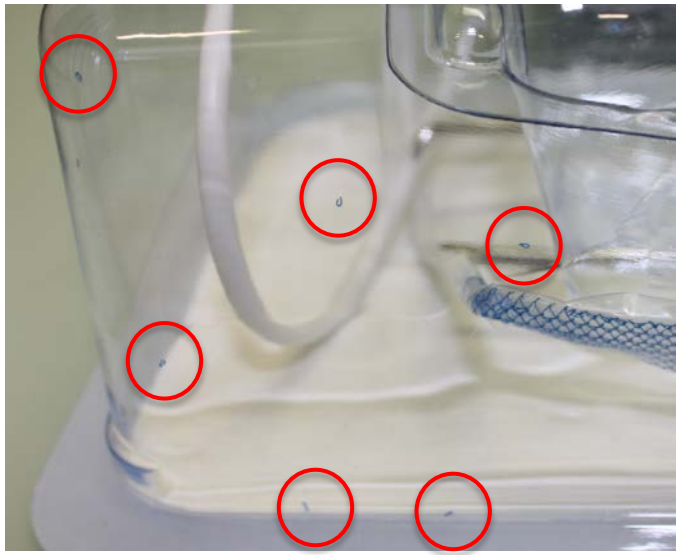
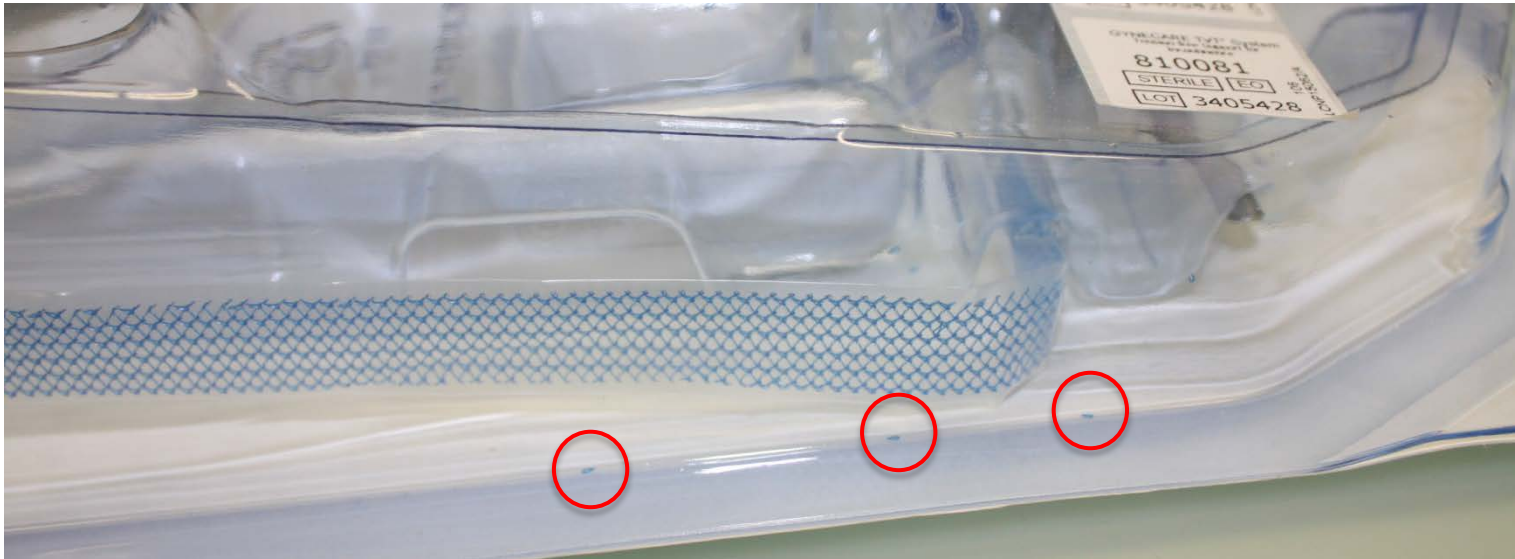
a Johnson & Johnson company

Pictures from complaint investigation



○ = Particle of Prolen mesh



Product Specifications

* Particle(s) belonging to the product in the blister (blue or white based on mesh being process) inferior to 0.4mm2 or 3mm is acceptable.

- Greater than 3 mm = class II defect
- Less than 3 mm = not a defect

* Particle(s) no belonging to the product in the blister is not acceptable

References : TM403-166 Appendix 9, EMQD10, VSE0007, C/L-E0038

TVTO Products

TVTO = 2 Product codes:

A manual code (810081) & A laser code (810081L)

↓ ↓

Prolen Mesh cut with a massicot (manual cutter)

Prolen Mesh cut with a laser

⇩

Blue and White particles of Prolene could be generated during cutting process.
(Frequency of occurrence is common per batch)

EXHIBIT A-3

From: Brennan, Carolyn [ETHUS] <CBrennan@its.jnj.com>
Sent: Tue, 05 Oct 2010 20:20:24 GMT
To: Chen, Meng [ETHUS] <MChen28@its.jnj.com>
Subject: RE: 10100124625 etc. - MEMO re TVT-O particles

Thanks Meng that works for me! I will ask Darlene to ID the files that this should go in. thank you!

Cary

Cary Brennan
Manager, Women's Health & Urology
Worldwide Customer Quality
E T H I C O N
a Johnson & Johnson Company
Phone: (908) 218-2017
Fax: (908) 218-2579

From: Chen, Meng [ETHUS]
Sent: Tuesday, October 05, 2010 4:14 PM
To: Brennan, Carolyn [ETHUS]
Subject: RE: 10100124625 etc. - MEMO re TVT-O particles

Cary: I added one sentence behind the previous one, see if you are fine with it now:

After careful review of the available information in the files and the information provided from the manufacturing site, the Business Unit Medical Director and I feel that the possibility for the tiny tape fragments observed in these five cases to cause adverse consequence in a patient, a device administrator or others should be considered remote. The presence of tiny tape fragments in the product package is not expected to change the product safety profile.

Let me know if this is better. Thanks, Meng

From: Brennan, Carolyn [ETHUS]
Sent: Tuesday, October 05, 2010 3:40 PM
To: Chen, Meng [ETHUS]
Subject: 10100124625 etc. - MEMO re TVT-O particles

Hi Meng. I've been asked to draft a letter to Taiwan responding to this issue. I did not make this meeting when you all discussed the issue but I know that you and Dave spoke. I think I will need additional comment

specifically that the device is safe to use – so I can communicate this piece to Taiwan. Would it be possible to update your comment with that piece?

Thanks!

After careful review of the available information in the files and the information provided from the manufacturing site, the Business Unit Medical Director and I feel that the possibility for the tiny tape fragments observed in these five cases to cause adverse consequence in a patient, a device administrator or others should be considered remote.

Cary

Cary Brennan
Manager, Women's Health & Urology
Worldwide Customer Quality
ETHICON
a Johnson & Johnson Company
Phone: (908) 218-2017
Fax: (908) 218-2579

EXHIBIT A-4

From: Lugo-Ponce, Carlos E. [ETHUS] <CLugo3@its.jnj.com>

Sent: Tue, 24 Aug 2010 13:11:16 GMT

To: Kyle, Darlene Jane [ETHUS] <DKyle5@its.jnj.com>; Armstrong, Shalot [JNJCH] <sarmstr2@ITS.JNJ.com>; Heron, Claire [JNJCH] <CHERON@its.jnj.com>

CC: Brennan, Carolyn [ETHUS] <CBrennan@its.jnj.com>; Chen, Meng [ETHUS] <MChen28@its.jnj.com>; Lisa, Bryan [ETHUS] <BLisa@its.jnj.com>; Brunner, Neal T. [ETHUS] <NBrunner@its.jnj.com>; Day, Melissa [ETHUS] <MDay4@its.jnj.com>; Robinson, David [ETHUS] <DRobin11@its.jnj.com>; Schmitt, Konrad [MEDDE] <KSchmit1@its.jnj.com>

Subject: RE: Product Complaint CC1007005-Taiwan

Darlene,

First, I recommend a meeting rather than an email chain.

Please note that before we decide any next steps, we need to discuss the complaint and more importantly the manufacturing evaluation.

Dr. Robinson, Neal Brunner and Bryan Lisa should be part of the meeting too.

Claire or Shay,

I suggest you take the lead, call the meeting and drive a resolution. We need a detailed understanding of how this happens in the manufacturing floor, what defect classification this is and how frequent this is? These answers need to be brought to the meeting.

Thanks and kind regards,

Carlos

From: Kyle, Darlene Jane [ETHUS]
Sent: Monday, August 23, 2010 11:12 AM
To: Lugo-Ponce, Carlos E. [ETHUS]
Cc: Brennan, Carolyn [ETHUS]; Armstrong, Shalot [JNJCH]; Heron, Claire [JNJCH]; Chen, Meng [ETHUS]
Subject: FW: Product Complaint CC1007005-Taiwan

Carlos,

Our affiliate in Taiwan has requested a letter to provide to her customer stating that our TVT-O is safe to use, despite the small pieces of mesh in the packaging (refer to complaint 10100122655). As you can see from the communications attached, this has been discussed by our group, the manufacturing site and Meng with a decision to bring it to your attention. Can you please assist our affiliate with this request?

Thank you.

Darlene

From: Chen, Meng [ETHUS]
Sent: Thursday, August 19, 2010 8:56 AM
To: Armstrong, Shalot [JNJCH]; Kyle, Darlene Jane [ETHUS]
Cc: Heron, Claire [JNJCH]; Brennan, Carolyn [ETHUS]
Subject: RE: Product Complaint CC1007005-Taiwan

Dear Shay: For this type of medical/clinical evaluation, it is usually requested through PMS (Carlos and Joe Scavona). They will then make a formal Health Hazard Evaluation Assignment to Dr. Robinson or Dr. Kirkemo. The HHE is usually completed by either doc fitting your specification. Please request Darlene to contact the PMS group. If they are not able to help, I will help to write up the evaluation as you wish. Does this help? Meng

---

From: Armstrong, Shalot [JNJCH]
Sent: Thursday, August 19, 2010 3:52 AM
To: Kyle, Darlene Jane [ETHUS]; Chen, Meng [ETHUS]
Cc: Heron, Claire [JNJCH]; Brennan, Carolyn [ETHUS]
Subject: RE: Product Complaint CC1007005-Taiwan

Darlene,

Can you pose this question to Meng. Per our defect classification this is part of the product and acceptable. If the customer is looking for an **official letter** to explain that the tiny pieces in the package does not pose the health risk and it's **safe to use,** this would need to come from R&D or medical affairs.

Meng,

Can you help us with this request. If necessary we can schedule a meeting.

Shay

From: Kyle, Darlene Jane [ETHUS]
Sent: Wednesday, August 18, 2010 8:51 PM
To: Armstrong, Shalot [JNJCH]; Heron, Claire [JNJCH]
Cc: Heramza, Céline [JNJCH]
Subject: RE: Product Complaint CC1007005-Taiwan

Shay,

You may be right. Let me know how Claire would like to handle and the correct contact.

Thank you.

Darlene

From: Armstrong, Shalot [JNJCH]
Sent: Wednesday, August 18, 2010 2:50 PM
To: Kyle, Darlene Jane [ETHUS]; Heron, Claire [JNJCH]
Cc: Heramza, Céline [JNJCH]
Subject: RE: Product Complaint CC1007005-Taiwan

Darlene,

I am not sure if this type of memo should be coming from the manufacturing site or from R&D. Let me speak with Claire first.

From: Kyle, Darlene Jane [ETHUS]
Sent: Wednesday, August 18, 2010 8:40 PM
To: Heramza, Céline [JNJCH]
Cc: Chen, Kathie [MEDTW]; Armstrong, Shalot [JNJCH]
Subject: FW: Product Complaint CC1007005-Taiwan

Celine,

When you get back to the office can you provide a letter to Kathie regarding the safety of the hand cut TVT devices with small pieces of the mesh in the package (see complaint 10100122655)? The Worldwide Customer Quality group cannot provide this type of documentation.

Feel free to contact me if you have any questions.

Thank you!

Darlene J. Kyle
Analyst, Worldwide Customer Quality
908 218-2792
dkyle5@its.jnj.com

From: Chen, Kathie [MEDTW]
Sent: Wednesday, August 18, 2010 7:03 AM
To: Kyle, Darlene Jane [ETHUS]
Subject: RE: Product Complaint CC1007005-Taiwan

Dear Darlene,
Thanks a lot for your efforts on this issue.
I'm wondering if you could provide us the **official letter** to explain that the tiny pieces in the package does not pose the health risk and it's **safe to use**?
We need to explain to our customers and convince them of product's safety and quality.
Besides, should we need to report this kind of complaint in the future?

Thanks a lot ,
Kathie

From: Kyle, Darlene Jane [ETHUS]
Sent: Wednesday, August 18, 2010 1:16 AM
To: Chen, Kathie [MEDTW]
Subject: FW: Product Complaint CC1007005-Taiwan

Complaint 10100122655 has been closed. The closure form is attached.

From: Kyle, Darlene Jane [ETHUS]
Sent: Tuesday, July 06, 2010 3:36 PM
To: Chen, Kathie [MEDTW]
Subject: FW: Product Complaint CC1007005-Taiwan

Kathie,

I have received the attached complaint and have entered the information provided into the complaint handling system under file 10100122655. Please send the products directly to my attention:

Darlene J. Kyle
Room G103-2
Ethicon
Route 22 West
Somerville, NJ 08876

908 218-2792

To facilitate product returns through customs, please utilize this information when sending the product:

Product Description: Tension Free Vaginal Tape/Pubourethral Sling
Manufacturer #: 2210968
510K/PMA #: K974098/K012628 / K052401
FDA Product Code: FTL
Product being returned for QA investigation

Thank you.

Darlene J. Kyle
Analyst, Worldwide Customer Quality
908 218-2792
dkyle5@its.jnj.com

From: Chen, Kathie [MEDTW]
Sent: Monday, July 05, 2010 6:57 AM
To: Kyle, Darlene Jane [ETHUS]
Cc: Heramza, Céline [JNJCH]
Subject: RE: Product Complaint CC1007005-Taiwan

Dear Darlene,
Thanks a lot for your mail.
Attached please find the MD&D form for this complaint.
Because all these four TVTO are complained from same hospital, we put these 4 cases into one complaint.
Please provide us the tracking number and we will return the products.

Thanks again,
Kathie

From: Kyle, Darlene Jane [ETHUS]
Sent: Saturday, July 03, 2010 1:20 AM
To: Chen, Kathie [MEDTW]
Subject: RE: Queries about TVT Obturator-Taiwan

Kathie,

No this is not normal nor do we recommend using the product. Please complete complaint forms for each and send for entry into the complaint handling system. Since the devices were not used they can be sent directly her once a complaint number has been assigned.

Thank you.

Darlene

From: Chen, Kathie [MEDTW]
Sent: Friday, July 02, 2010 6:53 AM
To: Kyle, Darlene Jane [ETHUS]
Subject: RE: Queries about TVT Obturator-Taiwan

Dear Darlene,
Today we received another 3 cases the same as yesterday. (Our customers are so angry about this)
I took another pictures for your reference.
<< File: 20100702.zip >>
Please let us know whether it's safe to use.
If this is the normal and safe condition, could you please provide us the formal declaration letter because we need to reply to our customer by next Monday.

Could you please forward this on, if you are not the appropriate person to deal with.

Thanks a lot for your help in advance.

Best Regards,
Kathie

From: Chen, Kathie [MEDTW]
Sent: Thursday, July 01, 2010 6:58 PM
To: Kyle, Darlene Jane [ETHUS]
Subject: Queries about TVT Obturator-Taiwan

Dear Darlene,
Good day! I have some quality queries about the product TVT Obturator System, could you please answer it for me?
Today our customer found some tiny mesh pieces (about 2 mm) in the unopened tyvek box.
So they refused to accept the product TVTO (Code:810081).
Could you please let me know why did these tiny mesh pieces fall within the sterile package?
Is this product with tiny mesh pieces safe to be used?

Attached please find the several pictures for this issue.
<< File: TVTO.zip >>
It's greatly appreciated for your reply, and thank you so much for your kind help.

Many thanks,
Kathie

Johnson &Johnson Medical Taiwan
Professional Affairs & Corporate Communications Dept.
6F. 319, Sec.2, Tun Hwa S. Rd, Taipei 106, Taiwan
Tel: +886-2-23764849/ FAX: +886-2-27386380

EXHIBIT A-5

From: Kyle, Darlene Jane [ETHUS]
Sent: Mon, 02 Aug 2010 17:23:29 GMT
To: Chen, Kathie [MEDTW] <KCHEN6@ITS.JNJ.COM>
Subject: FW: Product Complaint CC1007047&CC1007048-Taiwan (TVTO:810081)

Kathie,

Complaint CC1007048 has been entered into the complaint handling system.

This event was reported with four natures of complaint.

- Product complaint #10100124603 will hold all information regarding lot 3413119
- Product complaint #10100124604 will hold all information regarding tot 3413121
- Product complaint #10100124605 will hold all the information regarding lot 3389752
- Product complaint #10100124606 will hold all the information regarding lot 3389753.

To facilitate product returns through customs, please utilize this information when sending the product:

Product Description: Tension Free Vaginal Tape/Pubourethral Sling
Manufacturer #: 2210968
510K/PMA #: K974098/K012628 / K052401
FDA Product Code: FTL
Product being returned for QA investigation

Please send the product directly to my attention at:

Ethicon
Route 22 West
Room G103-2
Route 22 West
Somerville, NJ 08876

Thank you.

Darlene J. Kyle
Analyst, Worldwide Customer Quality
908 218-2792
dkyle5@its.jnj.com

From: Chen, Kathie [MEDTW]
Sent: Thursday, July 29, 2010 5:27 AM
To: Kyle, Darlene Jane [ETHUS]
Subject: RE: Product Complaint CC1007047&CC1007048-Taiwan (TVTO:810081)

Dear Darlene,
Attached please find the MD&D form for the other 6 boxes of TVTO with tiny blue mesh pieces inside the sterile package.

Please send me the tracking number that I will send the products back to you.

I would be appreciated if you could provide us the investigation result as soon as possible.
Thanks a lot for your help in advance.

Best Regards,
Kathie

From: Chen, Kathie [MEDTW]
Sent: Wednesday, July 28, 2010 7:49 PM
To: Kyle, Darlene Jane [ETHUS]
Subject: RE: Product Complaint CC1007005-Taiwan

Dear Darlene,
Do you have any updates or findings for this complaint?

Best Regards,
Kathie

From: Chen, Kathie [MEDTW]
Sent: Monday, July 19, 2010 6:00 PM
To: Kyle, Darlene Jane [ETHUS]
Subject: <Urgent> Product Complaint CC1007005-Taiwan
Importance: High

Dear Darlene,
Could you please let me know the status of investigation for this complaint?
Our customer continue to find another 5 boxes of TVTO with tiny blue mesh pieces and rejected to receive it.
All of these complaints made a great impact on our company's reputation.
Please help us investigate this issue and response to us ASAP.
Thanks a lot for your great help.

Best Regards,
Kathie

From: Chen, Kathie [MEDTW]
Sent: Friday, July 09, 2010 7:49 PM
To: Kyle, Darlene Jane [ETHUS]
Subject: RE: Product Complaint CC1007005-Taiwan

Dear Darlene,
I have sent the products back to you.
The FedEx tracking number is 8721 6345 0427.

When the investigation complete, please let me know the result as possible as you can.
As you know, we need to explain to our customer.

Thanks a lot.
Best Regards,
Kathie

From: Kyle, Darlene Jane [ETHUS]
Sent: Wednesday, July 07, 2010 3:36 AM

To: Chen, Kathie [MEDTW]
Subject: FW: Product Complaint CC1007005-Taiwan

Kathie,

I have received the attached complaint and have entered the information provided into the complaint handling system under file 10100122655. Please send the products directly to my attention:

Darlene J. Kyle
Room G103-2
Ethicon
Route 22 West
Somerville, NJ 08876

908 218-2792

To facilitate product returns through customs, please utilize this information when sending the product:

Product Description: Tension Free Vaginal Tape/Pubourethral Sling
Manufacturer #: 2210968
510K/PMA #: K974098/K012628 / K052401
FDA Product Code: FTL
Product being returned for QA investigation

Thank you.

Darlene J. Kyle
Analyst, Worldwide Customer Quality
908 218-2792
dkyle5@its.jnj.com

From: Chen, Kathie [MEDTW]
Sent: Monday, July 05, 2010 6:57 AM
To: Kyle, Darlene Jane [ETHUS]
Cc: Heramza, Céline [JNJCH]
Subject: RE: Product Complaint CC1007005-Taiwan

Dear Darlene,
Thanks a lot for your mail.
Attached please find the MD&D form for this complaint.
Because all these four TVTO are complained from same hospital, we put these 4 cases into one complaint.
Please provide us the tracking number and we will return the products.

Thanks again,
Kathie

From: Kyle, Darlene Jane [ETHUS]
Sent: Saturday, July 03, 2010 1:20 AM
To: Chen, Kathie [MEDTW]
Subject: RE: Queries about TVT Obturator-Taiwan

Kathie,

No this is not normal nor do we recommend using the product. Please complete complaint forms for each and send for entry into the complaint handling system. Since the devices were not used they can be sent directly her once a complaint number has been assigned.

Thank you.

Darlene

From: Chen, Kathie [MEDTW]
Sent: Friday, July 02, 2010 6:53 AM
To: Kyle, Darlene Jane [ETHUS]
Subject: RE: Queries about TVT Obturator-Taiwan

Dear Darlene,
Today we received another 3 cases the same as yesterday. (Our customers are so angry about this)
I took another pictures for your reference.
<< File: 20100702.zip >>
Please let us know whether it's safe to use.
If this is the normal and safe condition, could you please provide us the formal declaration letter because we need to reply to our customer by next Monday.

Could you please forward this on, if you are not the appropriate person to deal with.

Thanks a lot for your help in advance.

Best Regards,
Kathie

From: Chen, Kathie [MEDTW]
Sent: Thursday, July 01, 2010 6:58 PM
To: Kyle, Darlene Jane [ETHUS]
Subject: Queries about TVT Obturator-Taiwan

Dear Darlene,
Good day! I have some quality queries about the product TVT Obturator System, could you please answer it for me?
Today our customer found some tiny mesh pieces (about 2 mm) in the unopened tyvek box.
So they refused to accept the product TVTO (Code:810081).
Could you please let me know why did these tiny mesh pieces fall within the sterile package?
Is this product with tiny mesh pieces safe to be used?

Attached please find the several pictures for this issue.
<< File: TVTO.zip >>
It's greatly appreciated for your reply, and thank you so much for your kind help.

Many thanks,
Kathie

Johnson &Johnson Medical Taiwan
Professional Affairs & Corporate Communications Dept.

6F. 319, Sec.2, Tun Hwa S. Rd, Taipei 106, Taiwan
Tel: +886-2-23764849/ FAX: +886-2-27386380

EXHIBIT A-6

From: Jaccard, Jamil [JNJCH] <jjaccard@its.jnj.com>
Sent: Tue, 17 Aug 2010 14:52:06 GMT
To: Heron, Claire [JNJCH] <CHERON@its.jnj.com>
CC: Poulot, Stéphane [JNJCH] <spoulot@its.jnj.com>; Hostache, Karine [JNJCH] <khostach@its.jnj.com>; El Fettouhi, Atimad [JNJCH] <aelfetto@ITS.JNJ.com>
Subject: Particles in production

Bonjour Claire,

Suite à ta demande lors de la TAM, merci de trouver la présentation ci jointe :

Je reste à disposition pour toute question,

Meilleures salutations, Best Regards,

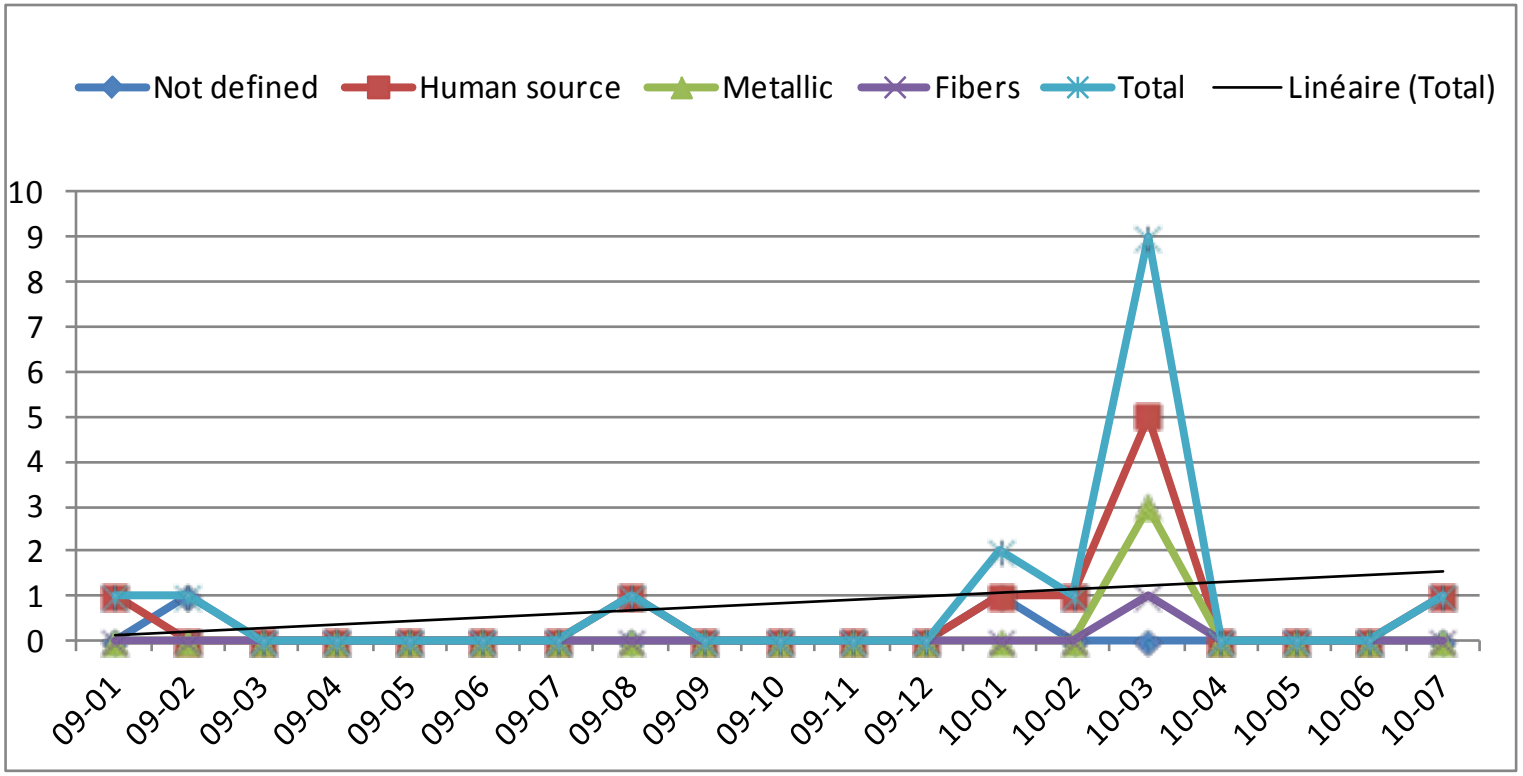
Jamil Jaccard
QA Engineer
ETHICON SÀRL
A Johnson and Johnson Company
Puits Godet, 20
2000 Neuchâtel - Switzerland
Tel : (+41) 32 934 86 96
Fax : (+41) 32 934 86 10
Email: jjaccard@its.jnj.com

Placeholder

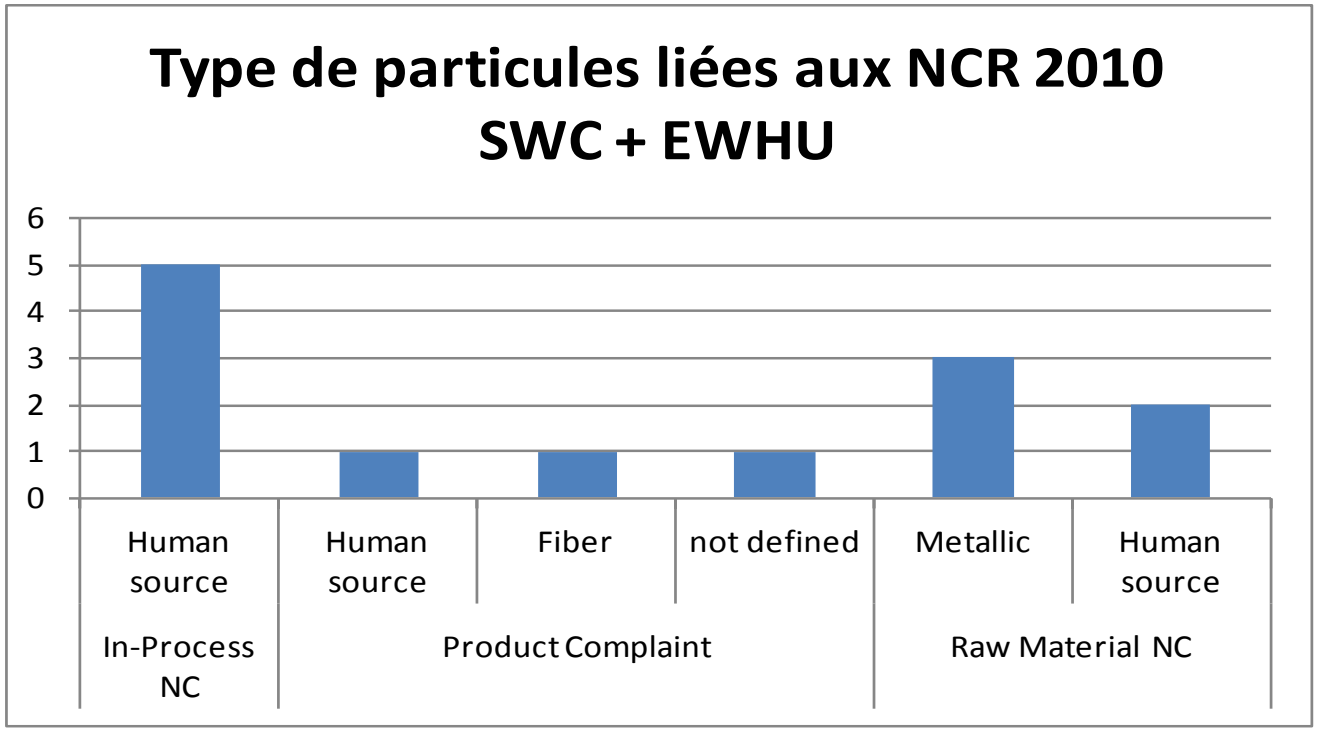
Document produced in native format

EVOLUTION DES NC ET REJETS LIÉS AU « FOREIGN MATTER » SUR SWC ET EWHU EN 2010

EVOLUTION DES NCR LIÉES A DES « FOREIGN MATTER » DEPUIS 2009 SUR NEUCHÂTEL :

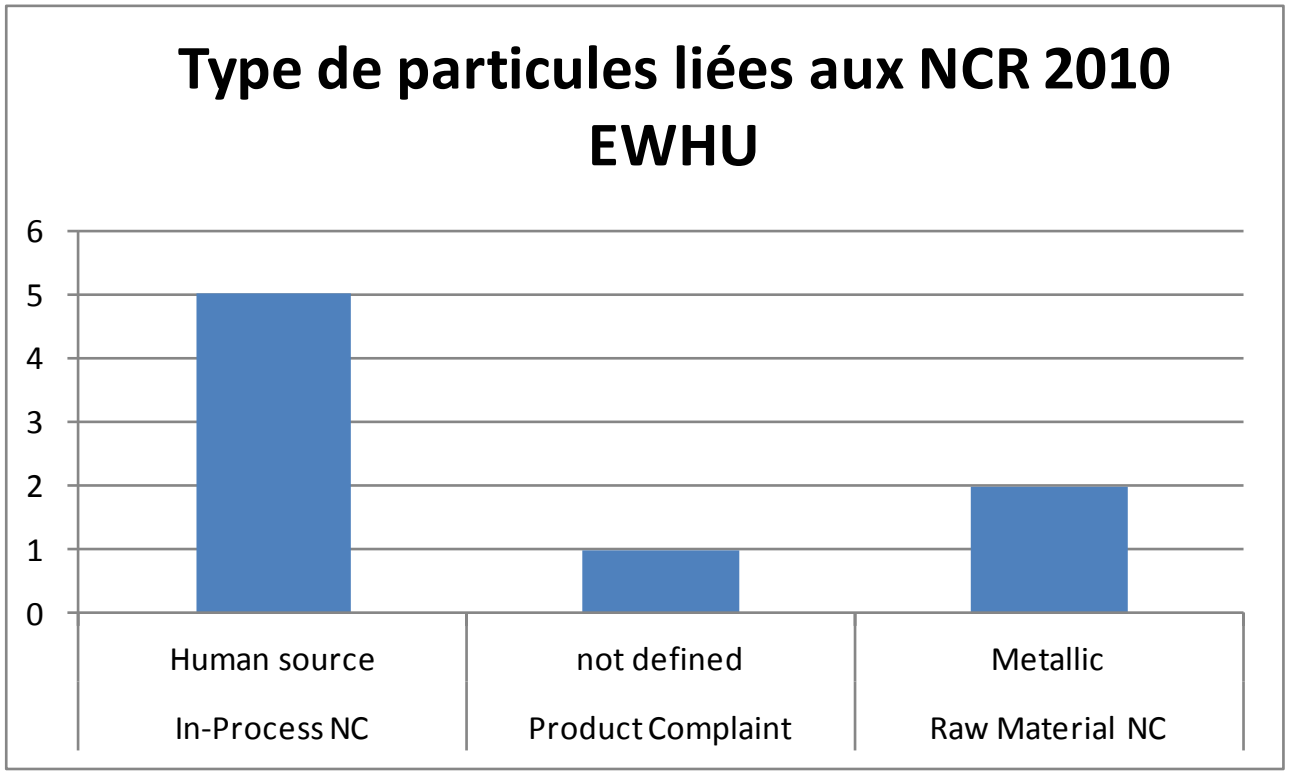


TYPE DE FOREIGN MATTER A L'ORIGINE DES NCR, SWC + EWHU EN 2010 :



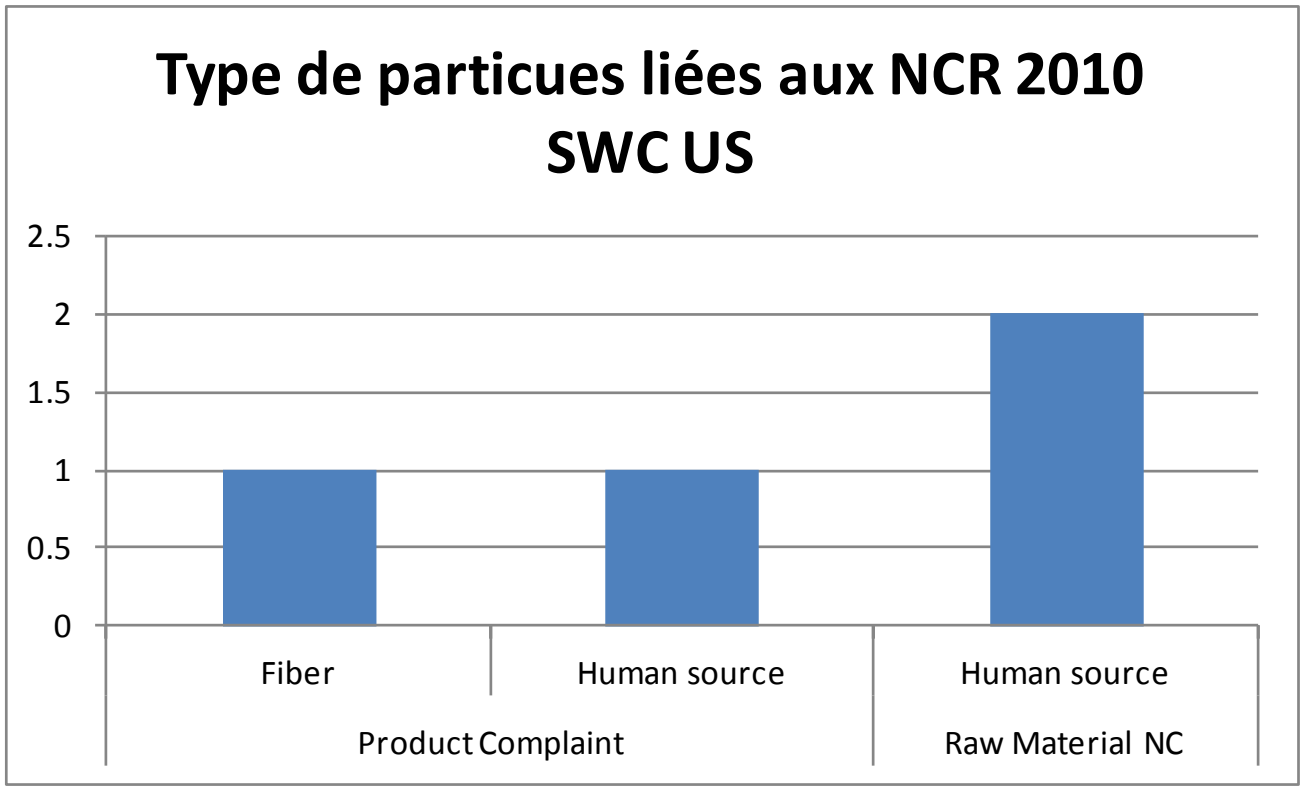
- Rem : Metallic sont liés au problème d'aiguille TVT

2.1) UNIQUEMENT SUR EWHU :



- Rem : Metallic sont liés au problème d'aiguille TVT

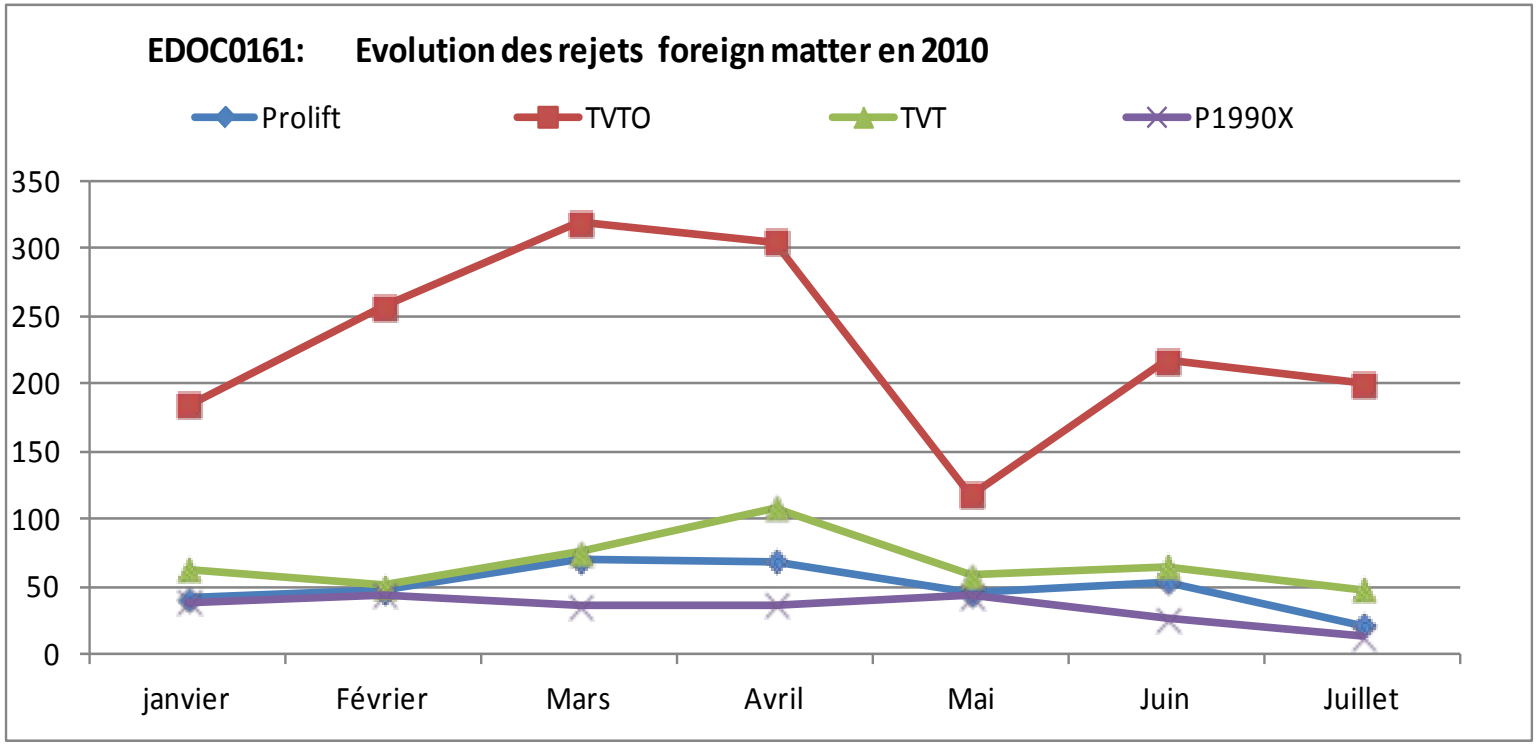
2.2) UNIQUEMENT SUR SWC US



2.3) SWC EMEA PAS DE NCR EN 2010

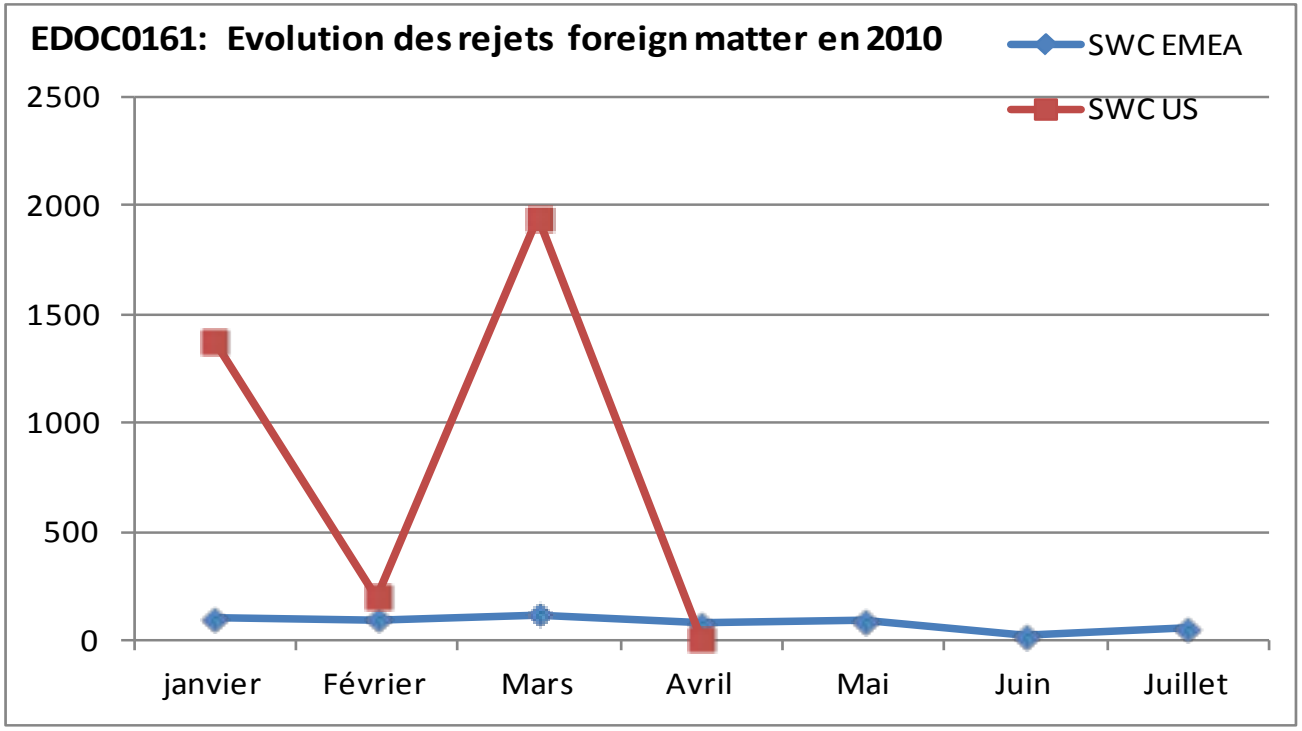
3.) **EDOC0161** EWHU 2010 :

(NE PERMET PAS DE SAVOIR LE TYPE DE FOREIGN MATTER)



3.2) EDOC0161 SWC

(SWC US Avec du retard depuis avril)



- (SWC US A du retard depuis avril)

CONCLUSIONS:

- Un gros pic de NCR en Mars a mis en évidence le problème des Foreign Matter en salle.
- La principale source est humaine pour tous les types de NCR (In process/ complaint/ Raw mat)
- Les rejets de composant en salle (selon EDOC161) sont stable en 2010.
- Selon le Nb de NCR et les EDOC0161, SWC US est plus sensible aux particules (ou saletés) que SWC EMEA.

EXHIBIT A-7

ETHICON Inc.
a Johnson & Johnson company

Document Name (#): PR-0000118
Revision: 14

FRANCHISE PROCEDURE FOR PRODUCT COMPLAINT MANAGEMENT

Revision History for PR-0000118

Revision #	Summary of Change	Change Order #	Originator
14	Procedure update to align with new PR-0000368, Franchise Procedure for Tracking and Trending Quality Systems Data. Revisions were made to the tracking and trending section of this procedure.	CO-0024590	A.Murphy
13	Procedure update to reflect the complaint investigation review process steps from PR-0000237 performed on Serious Injuries, Deaths and/or incidents. Minor editorial changes to Appendix I and Definitions/Acronyms.	CO-0023195	A. Murphy
12	Procedure updated in include Aurangabad (India) as a complaint handling unit	CO-0023025	G. Pensak
11	Update procedure to reflect minor update to Complaint Handling Units on section 2.	CO-0022823	G. Pensak
10	Update procedure to reflect WCQ as the designated complaint handling unit for products manufactured out of the Ethicon LLC (Guaynabo, Puerto Rico).	CO-0022080	G. Pensak
9	Update procedure to reflect updates associated process and application updates.	CO-0021873	G. Pensak
8	Procedure Re-write related to complaint handling process as indicated. Plus updated reference as part of the MedDev (Rev. 5) Guideline update.	CO-0018248	G. Pensak
7	Update procedure to reflect escalation	CO-0014633	L. Blanco

	process from Critical Complaint to potential PQI. Update definition table by removing Critical Complaint definition and adding Product Quality Issue (PQI) definition. Add comment regarding Brazil complaints.		
6	Included additional instructions on documentation of complaints using the Remetrex PQMS application	CO-0012794	Jrosado3

**Indicates a change
// Indicates a deletion

1 Purpose

- This procedure defines the methods and responsibilities for investigating, documenting and evaluating all complaints about ETHICON Franchise products. These complaints are processed for domestic and international companies worldwide including contract manufacturers and external manufacturers involved in the production of ETHICON Franchise products. To that end, this procedure defines the practices for handling complaints for products for which ETHICON is the manufacturer or the distributor.
- Inquiries of our products or services will be directed to the most appropriate sources within this company to provide a responsible answer to our customers.
- All communication and documentation related to product complaints and/or product liability, with either the customer and/or sales representatives must be coordinated through the designated Complaint Handling Units (CHU). All communications must be documented and maintained in accordance with the FDA Quality System Regulation, the European Medical Device Directive (MDD 93/42) and the local Medical Device Legal Requirements as per global quality manual PL-0000001.
- All product complaints requiring corrective action will be entered into the CAPA system.
- Complaint data are compiled, trended, and analyzed to continuously examine opportunities for further improvement on existing product designs as well as in our product manufacturing operations. These data are communicated periodically to management and other appropriate personnel.
- All complaint data will be captured in Central Global Database, regardless of origin of complaint and complaint handling unit investigating complaint. The Worldwide customer Quality (WCQ) group is designated as owner of this database.
- WCQ group owns responsibility of complaint review with Global management, though individual designated complaint handling units own responsibility of review with local management and Legal Manufacturer.
- It is the responsibility of Ethicon Management to take whatever actions it deems necessary to reduce and eliminate negative complaint trends.
- Records of all complaints and associated documentation are contained in complaint files at designated complaint handling units and in the Remetrex complaint handling system.

2 Scope

This procedure applies to product complaints involving products manufactured and/or distributed by ETHICON Franchise business units and sites as defined in ETHICON Franchise Quality Manual. All ETHICON Franchise associates who are involved in the complaint handling process will execute the process.

Designated Complaint handling units: Locations of designated complaint handling units include Somerville NJ (USA), Sao Jose dos Campos (Brazil), Livingston (UK), Norderstedt (Germany), Auneau (France), Aurangabad (India), and Gargrave (UK), for applicable products.

3 Definitions, Acronyms and Abbreviations

Term	Description

Term	Description
Acknowledgment Communication	A communication acknowledging the receipt of a product complaint by the company (i.e. Letter, email, etc.).
Adverse event	Any undesirable experience associated with the use of a medical product in or on a patient, whether or not considered product related
Adverse Event / Incident report timelines	Timelines for when adverse events are reported to regulatory bodies. For FDA MDR events (death, serious injury or malfunction) typical reports are 30 days from alert date. For case where field corrective action is taken, these should be reported within 5 days. Medical Device Vigilance Incidents (MEDDEV) are to be reported as follows: Serious public Health threat: Report immediately within 2 calendar days Death or Unanticipated serious deterioration in state of health: Report immediately after a link between the device and the event has been established, but not later than 10 calendar days Others: Report immediately after a link between the device and the event has been established, but not later than 30 calendar days. For Canadian MDR's, reports are made in 10 or 30 days based on incident severity. Other local reporting timelines may exist and each country should follow their specific requirements.
Alert Date	Date used for purposes of Adverse event / Incident reporting (MDR/MDV). This is date that any Johnson & Johnson employee becomes aware of an adverse event which may involve a product manufactured by or for ETHICON.
Authorized representative	Person or firm given permission to act or operate on the company's behalf The European Authorized Representative (EAR) means any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this Medical Device Directive.
Closure Communication	A summary of the complaint investigation that is communicated to the appropriate party involved. Communication of the closure serves as the customer closeout of the complaint, unless the representative or customer determines that additional actions are needed
Complaint Closed Date	Date complaint file is closed by CHU after all activities have been completed and final communication to customer
Complaint Open Date	Date complaint file is initiated at CHU. This date may differ from Alert Date
Complaint open	Time in days calculated between complaint open and complaint

Term	Description
duration	closed date
Complaint/Event Rate	Number of complaints/events versus sales or manufacturing volume in eaches.
Confirmed Complaint	A complaint is confirmed when the evaluation results demonstrates that customer, Ethicon or Legal requirements were not met.
Unconfirmed Complaint	A complaint is unconfirmed when the evaluation results do not demonstrate that customer, Ethicon, or Legal requirements were not met.
Contract distributor	Person or firm that is not under direct control of the operating company, who distributes product on behalf of the operating company. Distributor means any person who furthers the distribution of a device from the original place of manufacture to the person who makes delivery or sale to the ultimate user, i.e., the final or multiple distributor, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package.
Contract sites	External facilities, outside of direct company control, hired to perform activities, according to specific agreements with the company
Corrective and preventive actions	Refer to Procedure PR575-001
Decision tree	Graphical representation of a series of yes/no queries, the response to which determines which path to follow to arrive at next action step or decision
Decontamination	A process of cleaning and /or disinfection of customer returned devices (used or un-used).
Designated Complaint Handling Unit (CHU)	Group designated by Legal Manufacturer at operating locations which has responsibility for management of complaint process.
Device History Record Review	Documented review of compilation of records as part of investigation to support conclusion of product complaint. Also may be referred to as Batch or Lot history review.
Diagnostic	Relating to or aiding in establishing or confirming a diagnosis of a disease or disorder.
Due Diligence	Conscientious attempts made to gather all data necessary to do a thorough investigation of each complaint.
File Owner **	Individual designated by Legal Manufacturer at CHU's who has responsibility for management of complaint files per the complaint process.
Incident	Death or any undesirable experience such as serious deterioration in the state of health of a patient, of the user or any other person, when considered as product-related, or any undesirable experience which might have led to death or serious deterioration in health.
J&J International Direct Company	J&J Company which is covered under management of ETHICON Franchise as described in ETHICON Franchise Quality Manual
J&J International Umbrella Company	J&J Company outside of the ETHICON Franchise
Japan PAL	Japanese Pharmaceutical Affairs Law

Term	Description
Legal Manufacturer	"Legal manufacturer" means the natural or legal entity with responsibility for the design, manufacture, packaging and labeling of a device before it is placed on the market under their own name, regardless of whether these operations are carried out by that entity or on their behalf by a third party.
Media	Scientific journal or peer review article and or healthcare professional discussion in an internet news group or chat room
Medical Device Vigilance (MDV):	The reporting of incidents / near incidents or decisions of systematic recall caused by malfunction or deterioration of product characteristics, product performance, labelling or instructions for use omissions or deficiencies (European Regulation).
Product Complaint	A written, electronic or oral communication that alleges deficiencies related to the identity, labeling, quality, durability, reliability, safety, effectiveness, or performance of any Ethicon device after it is released for distribution.
Product Event	If multiple occurrences of product issues occur during a single patient/user procedure, each of these product issues is deemed a product event and the total number of product events should be captured in complaint files (multiple occurrence / multiple products)
Product or Technical Inquiry	A question relating to the medical or technical application of an ETHICON product or a request for information which does not fall under the definition of product complaint.
Product Quality Issue (PQI)	A significant quality issue for which product has been distributed to the field where there is a potential health hazard and /or compliance risk that may require mitigation / field action.
Putting into service	"Putting into service" means the stage at which a device is ready for use on the market for the first time for its intended purpose.
Replacement	Product sent to end-user in replacement of complained product, when requested.
Representative sample	Product samples from same lot as product complaint sample.
Safety Officer	Qualified person responsible for collection, assessing and coordinating appropriate measures and activities in regard to complaint handling (German Medical Device Law).
Stop Shipment/ Product Hold	An order to a J & J distribution center/ affiliate to halt shipment of products, due to a quality reason, which affects availability of product for sale. Stop Shipment/ Product Hold is temporary action. It either can be removed if the discrepancy is determined not to affect safety, reliability or efficacy of the product, or can lead to other action such as rework, field correction, recall depending upon outcome of analysis and discussion with Director of Quality. If no further action is deemed necessary, rationale for the same needs to be documented and product released to market.
Synergy	J&J Corporate system for initiation of complaints by J&J Umbrella marketing affiliates and for J&J MD&D companies to report complaint investigation resolutions back to marketing affiliate.
Therapeutic	Relating to or aiding in treatment, remediating or curing of a

Term	Description
	disease or disorder

4 Roles and Responsibilities

Manager of Worldwide Customer Quality (WCQ) maintains this procedure

The designated CHU is responsible for transposing global franchise procedure into local work instructions and to establish and maintain a complaint handling system, which is in compliance with J&J Policy and guidelines as well as applicable national law.

Detailed responsibilities in regard to entire process (complaint initiation, investigation, CAPA, information to customer, event / incident reporting etc.) are demonstrated in the following table

Function / Role	Responsibilities
Complaint initiation	Customer
Open complaint file	CHU at location which puts product into service
Adverse event / Incident Decision	Legal Manufacturer decides with CHU on reporting to Competent Authority taking local laws into consideration (e. g. Safety Officer / Germany)
Adverse event / Incident Reporting	Legal Manufacturer decides with CHU on base of local procedures who creates report (e. g. subcontractor)
Information about Incidents within EU to be forwarded to Authorized Repr.	Legal Manufacturer designated subcontractor
Complaint investigation	Legal Manufacturer designated subcontractor
Acknowledgement Communication	CHU (more specifically defined in local procedures)
Sample Return	J&J International Umbrella Company, or as applicable
Sample Decontamination	Performed as per J&J Guidelines
Sample Evaluation	Performed per applicable site or manufacturer procedures
Perform Investigation Escalation (NCR application)	Refer to PR-0000256, as applicable
Perform Corrective and Preventive Action (CAPA application)	Refer to PR575-001, as applicable

Function / Role	Responsibilities
Review Complaint File	CHU at Legal Manufacturer designated subcontractor
Complaint Closure with Customer	CHU (more specifically defined in local procedures)
Definition of Tracing No. for each complaint	CHU at Legal Manufacturer designated subcontractor
Local complaint tracking and trending	CHU at Legal Manufacturer designated subcontractor
** Global complaint tracking and trending	Post Market Surveillance Associate or Designee
Creation and maintaining complaint categories / types	Refer to Procedure PR-0000114 and PR-0000119.

5 Procedure

5.1 Process overview:

Appendix I contains flow chart showing global overview of complaint management process for ETHICON franchise

Appendix II contains process flow chart for activities which occur at individual CHU

5.2 Complaint management procedure:

5.2.1 Complaint origination: The following list captures possible originations of customer complaints

- Customer contacts CHU directly
- CHU is notified by J&J Umbrella company representative via Synergy form or other means.
- Regulatory body contacts CHU reporting customer reported adverse event
- Customer contacts J&J sales representative who contacts CHU
- J&J employee becomes aware of media (such as internet, journals, articles) describing product issue and contacts CHU
- J&J employee becomes aware of a product issue during a post market clinical trial.
- Customer contacts external manufacturer who contacts CHU
- Customer contacts regional call center and call center contacts CHU
- Any Johnson & Johnson Employee

5.2.2 Complaint file initiation

- Once CHU is notified of customer event, a complaint file is opened to capture all information

- An acknowledgement communication is provided unless the customer who initiated the complaint expressly does not wish this contact.
- If acknowledgement communication is performed, then the document, if applicable, should be scanned or saved, and attached to the "Attachments" page in the complaint file. However, a CHU can opt not to complete this task and instead keep a hard copy of the document on a physical file at the CHU location, as detailed by local procedure. Complaint Handling Unit will need to document the complaint file when information has been physically archived in the Investigation Comments section.
- The complaint will be entered into the Remetrex system via the "Issue Insert" tab.
- Each customer complaint is given a unique identifying / tracking number
- Product replacement / customer credit: Each CHU has different policies on product replacement and credit. If the process requires documentation of the completed replacement or credit, the appropriate reference information should be documented in the complaint file.

5.2.3 Minimum information required in complaint file (**Note: In the Remetrex Application, recommended information fields or sections are highlighted in "yellow")

- All information gathered via a product complaint or Synergy form. Minimum information requested is located in Appendix 3.
- Information on number of product events which may have occurred from single patient/user event
- All correspondences with customer in regards to complaint
- Complaint investigation results should be entered in the Investigation Comments section
- Adverse event report if applicable
- Product complaint category
- If the complaint is received in a written format, the source document should be scanned and attached to the complaint file in the attachments section. However, a CHU can opt not to complete this task and instead keep a hard copy of the document on a physical file at the CHU location, as detailed by local procedure. Complaint Handling Unit will need to document the complaint file when information has been physically archived in the Investigation Comments section.
- Product test results should be inserted in the Product Analysis section

5.2.4 How to choose the responsible CHU:

- The complaint numbering system in Remetrex will generate a CHU specific identification prefix, depending on the "company" selected as the owner of the complaint file in the "Issue insert" Page. This is followed by a sequential value. The prefix numbering system is set up as follows:
  - Ethicon Germany- 1020
  - Ethicon France- 1050
  - Ethicon UK- 1040.
  - Depuy-Mitek USA-2010
  - J&J Professional Products Brazil (Ethicon Brazil)- 4010
  - Ethicon India - 1060
  - Ethicon USA - 1010 (Includes Ethicon Women's Health and Urology, Ethicon Products USA, J&J Wound Management USA, and Closure Medical

Selecting responsible CHU:

- Ethicon Women's Health and Urology: All complaints for EWHU entered as "Ethicon USA" complaints.
- Ethicon LLC (Guaynabo, Puerto Rico), which includes products manufactured in San Lorenzo Puerto Rico and Juarez, Chih., Mexico, will be opened as "Ethicon USA complaints". WCQ will responsible for the complaint investigation, vigilance reporting and closure of the complaints on behalf of Ethicon LLC (Guaynabo, Puerto Rico).
- J&J Wound Management:
    - Neuchatel manufactured products are entered as "Ethicon USA" Complaints.
    - USA manufactured product is entered as "Ethicon USA".
    - Externally Manufactured product must be entered as "Ethicon USA".

- Ethicon Products:
    - USA and Mexico manufactured product is entered as "Ethicon USA" complaints.
    - European manufactured products are opened as follows:
        - Local CHU will own all EPD complaints reported to them, regardless of manufacturing site in Europe. Assignments for lot reviews and other tasks will be sent according to local procedure.
    - Brazil manufactured product is entered as "São José dos Campos, Brazil" complaints. Assignments for lot reviews and other tasks will be sent according to local procedure.
    - India manufactured product in entered as Aurangabad complaints. Assignments for lot reviews and other tasks will be sent according to local procedure(s).
    - If manufacturing site is not known: The complaint will be open according to the most current manufacturing location, in the case of transfers, or to the most likely manufacturing location, given the product distribution. Otherwise, enter it as a "Ethicon USA" complaint.
    - Closure Medical: Will be opened as "Ethicon USA complaints".
    - Ethicon LLC (Guaynabo, Puerto Rico), which includes products manufactured in San Lorenzo Puerto Rico and Juarez, Chih., Mexico, will be opened as "Ethicon USA complaints". WCQ will responsible for the complaint investigation, vigilance reporting and closure of the complaints on behalf of Ethicon LLC (Guaynabo, Puerto Rico).
    - Post Market Clinical Studies: All worldwide post market clinical studies (except for IDE studies) will be routed by the clinical group to WCQ in New Jersey for entry into Remetrex. WCQ will open file for the appropriate CHU following the above guidelines.

5.2.5 Number of complaint files to open:

- One complaint file will be opened per patient event reported.
- Each complaint file will contain one complaint category only.

- When multiple patient events are received on a single customer report or checklist, each individual complaint file will reference the other "sibling" complaints files.
- When multiple patient events (on same patient) are received that involve known multiple lots, a complaint must be opened for each lot identified.
- If one patient event contains multiple products referenced, they can be inserted in the complaint file. However, if the specific product is not known, then the practice for documentation will be to assign the appropriate "unknown code" (ie 99999 code) as primary product, and the additional products as references in the "Prod Info" page. The complaint category will be thus associated to the "unknown code".
- Complaints subject to FDA "Summary Reporting" guidelines: Ethicon has approval from FDA to report specific complaints via a quarterly summary instead of individual Medwatch reports. In those cases where a complaint has a quantity involved greated than "1", WCQ in New Jersey will open additional files (one per device reported) in order to be able to complete the report (Individual complaint numbers are required by FDA for summary reporting.). WCQ will notify CHU of this action and will document rationale in the complaint files.

5.2.6 Complaint Investigation: Complaint investigation may consist of several independent activities. These activities are all focused on the determination of the relationship of the device to the event reported and determination if the device failed to meet requirements.

- Information related to the complaint should be entered in the Investigation Comments section, as appropriate.

- Return product: Wherever possible, the actual device implicated in product complaint should be returned and evaluated. If actual sample is not available, other products from same lot may also be evaluated (representative sample).

- For files for which product is returned, the Qty Rec'vd field must be updated to indicate the quantity returned for evaluation purposes.

- Return product decontamination: All open used and unused returned products must be decontaminated per J&J corporate guidelines.
  - CHU is responsible for local procedure or work instruction in regards to product decontamination, including development of special packaging for the return of used devices as applicable.
  - CHU is responsible to forward decontaminated product to appropriate site for evaluation if possible.
  - Return product evaluation:
    - Visual and/or Functional testing – returned product may be visually examined and/or functional tested using appropriate test method.

  - Product evaluation report: All product complaint evaluations will be documented in the complaint file. Evaluation results should be directly entered into Remetrex (product analysis section), and the

report attached to the complaint file, where applicable. Minimum information to be contained in report/file includes:

- Complaint file number
- Test method(s) used for evaluation
- Number of samples tested
- Results summary
- Conclusion including statement in regard to confirmation CAPA / Not CAPA reference (for External Manufactured Product Only)

- If no report is generated, the information will be inserted in the respective sections of the complaint file.

5.2.7 Device history record (DHR) review

If Product information (product code and lot or serial number) is available, the DHR for the product should be reviewed, if deemed necessary. This may include finished good, in process or raw material review. Determination of level of review is made by local QA and related to complaint defect category

- DHR reviews should be performed for reportable files, if the batch number is known.
- When there are no sample(s) returned for evaluation and batch number is known, DHR review should be performed.
- CHU should forward request for DHR review to appropriate manufacturing location.
- DHR review results to be captured in complaint file

DHR reviews are not required when product has been returned for evaluation or when the batch number is unknown or has not been provided.

5.2.8 Medical Review

- Review may be requested to help in determination of device relationship to reported event, to determination of severity of an event for purposes of adverse event reporting.
- All Medical Review requests should be addressed to WCQ Associate Medical Director or designated MD for completion.
- WCQ Associate Medical director will coordinate with other Business Unit Medical directors as appropriate.
- All medical reviews are to be captured in the complaint file.

5.2.9 Due diligence: Every attempt must be made to gather all data necessary to do a thorough investigation of each complaint. If initial contact does not capture necessary information, below are guidelines for customer follow up in case no requirements are defined in local procedures.

- Customer follow-up attempts should be entered within the complaint file (i.e. Investigation Comments)
- Initial follow up within approximately 7 days of complaint open date to gather additional information as required and to repeat request for product return if return has not been received.

- Second follow up within approximately 14 days of complaint open date if information not yet received
- Final follow up within approximately 21 days of complaint open date
- At least one of the follow-up items should be in written format.
- File closure may be initiated after approximately 28 days if no additional information or return product has been received from the customer.
- All customer correspondence for due diligence should be captured in the complaint file.
- Re-Open file – Complaint file will be re-opened if after at any time after closure if additional information or returned product for evaluation is received from customer.
- Follow Up requests: The CHU that owns the complaint will be responsible for performing information and due diligence follow-ups. However, in files where a second CHU is collaborating, follow up can be performed by the second CHU as long as the CHU that owns the complaint is in agreement.
- Each complaint file should have the due diligence history documented in the complaint file.
- Assignments: For assigning tasks to individuals with access to the Remetrex system, the user will create an Assignment in the "assignments" tab in the complaint file. The assignment will be made to either the individual user ID, or to a generic CHU user name that has been pre-set in the system. The assignee is responsible for completing the task within the time allotted and will close the assignment once the task has been completed and documented in the complaint file.
- Complaint file information may be limited for those files that are in litigation status. Information related to complaint will be obtained as part of the Discovery process, as it becomes available.

5.2.10 Adverse Event / Incident reporting (MDR/MDV)

- Adverse Event / Incident Reporting is part of complaint management process, but is controlled via separate procedures for Adverse event / Incident reporting and per applicable local regulatory requirements. Refer to PR566-005 and PR551-006 for guidance information.
- Each CHU is responsible for procedure / work instruction for Adverse event reporting.
- All decisions, reports or other documents related to adverse event / incident reporting are to be captured in the complaint file.
- All applicable Vigilance reports for Incident and FDA Medwatches for Death and Serious injuries must be reported to JJKK per franchise procedure for adverse event reporting for Japan PAL requirements PR-0000204
- Complaints that are determined to be Serious Injuries, Death, and / or Incident, are subject to an additional complaint investigation review.
- MDV Determination: The MDV determination will be completed by the complaint handling unit that owns the complaint, as appropriate.
- MDV assignments for exceptions will be made to the appropriate CHU for MDV decision tree completion.
- MDR Determination: MDR determination for Ethicon Franchise complaints, regardless of CHU owner, will be completed by WCQ in New Jersey. WCQ will

not perform MDR determination for products that are not legally owned by Ethicon, unless indicated to be responsible as per Quality Agreement.

- MDR Determination assignment will be transferred to Ethicon USA.
- MDR Medwatch report will be completed and submitted by WCQ in New Jersey. CHU's will be notified when task is completed by WCQ in New Jersey.
- Follow Up information: If additional information is received and documented in the analysis or comments sections of the complaint file, the system will automatically generate a "review file " assignment. The CHU that owns the complaint will review the information and determine if MDV decision needs to be revised. System generated assignment will then be transferred to Ethicon USA for MDR determination or follow up Medwatch review.

5.2.11 Serious Injuries, Deaths, and /or Incidents

For complaint files (excluding files created as a result of literature reviews, internet searches and litigation files) that are determined to be Serious Injuries, Deaths and /or Incidents, a further Complaint Investigation Review (CIR) will be performed to draw:

- A Medical Assessment conclusion determining the relationship of the device to the reported event.
- A Quality Investigation conclusion determining whether or not the device met specifications.

5.2.11.1 Remetrex will automatically trigger a "CIR Reminder" assignment to the complaint File Owner to ensure that due diligence activities have been completed and documented. Once due diligence activities are completed and documented in the complaint file, the "CIR Reminder" assignment should be closed.

5.2.11.2 Upon closure of the "CIR Reminder" assignment, Remetrex will automatically trigger a "CIR Quality Investigation" assignment to the File Owner or designee for a quality investigation review and a "CIR Medical Assessment" WCQ Medical Director or designee for a medical assessment.

5.2.11.3 Quality Investigation Review: The following elements will be performed as applicable:

- Device History Record (DHR): A DHR review will be performed when a lot # is provided.
- Complaint History Review (CHR): If product information (a lot or serial number) is available, then a CHR will be performed and documented in the investigation comments. The CHR will be based on complaint category and batch number as appropriate.
- Returned Product Evaluation (RPE): A RPE will be performed when product is returned.
- Complaint Trending: If a DHR or RPE is not performed, a Trend Analysis will be conducted.
    - The File Owner will place a "Trend Analysis" assignment to the Post Market Surveillance (PMS) representative or designee.

5.2.11.3.1 Based on a review of the applicable quality investigation elements, a conclusion will be drawn by the File Owner or WCQ designee and

captured in the investigation comments of the file with one of the following statements (Refer to Appendix IV for definitions):

- Based on the review of the applicable quality elements, the device met Specifications
- Based on the review of the applicable quality elements, the device did not meet specifications
- Based on the review of the applicable quality elements, it cannot be concluded that the device did not meet specifications

5.2.11.4 Medical Assessment: For the reported event, the WCQ Medical Director will write a medical assessment based on the reported complaint information and include one of the following conclusions in the investigation comments (refer to Appendix V for definitions):

- The Device Caused Event
- The Device Contributed to Event
- The Device Potentially Contributed to Event
- The Device Not Likely Related to Event
- The Device is Not Related to Event
- Not Enough Information to Draw a Conclusion

5.2.11.5 Escalation of a Complaint Investigation Review

- If a complaint investigation review conclusion is determined to require escalation based on the quality review conclusion and/or the medical assessment review conclusion, the file owner or designee should notify their management as appropriate and document a clarifying statement within the investigation comments.

5.2.12 Investigation – Escalation for NCR/CAPA

- Once the Complaint Investigation has been completed, further (manufacturer's) investigation may be required.
- If Investigation escalation is performed, then the reference number should be documented in the Remetrex system in the field named Investigation Reference.
- The complaint file contains an investigation pertinent to the issue identified. Should additional investigation be required as per the table below, it will be escalated to the NCR and/or CAPA and will be referenced accordingly.
- Information related to the assignable cause and/or corrective and preventive actions will reside in the respective NCR and CAPA systems. The CAPA and/or NCR number will be referenced in the complaint file.

Further Investigation Determination Table

If complaint	Then
is confirmed for an internally manufactured product	Request a Manufacturer Investigation according to PR-0000256.
is confirmed for an externally	Request a Manufacturer Investigation

manufactured product	according to PS-0000473.
is for capital equipment	Refer to PS-0000473.
is unconfirmed	No further action is required unless QA Management decides that the information within the file requires further investigation. If further action is decided, request a Manufacturer Investigation according to PR-0000256.
generates a negative trend	QA Management will analyze trend and decide if a CAPA Request is required. If so, follow PR575-001 to initiate a CAPA Request.

NOTE: The reference number to a Manufacturer Investigation file or a CAPA Request will be documented in Remetrex-CHATS in the field named Investigation Reference.

NOTE: If there is an existing CAPA file open for a specific complaint issue, other complaints may be added to the CAPA file provided the complaint mode is identical.

5.3 Complaint File / Complaint Closure

- Each complaint file has to be complete and accurate.
- Each complaint file will be investigated separately and may contain reference to complaint files if the investigation activities are applicable to the references files. If they are not applicable, they will be investigated and documented appropriately.
- Closure Letter/Communication may contain references to other complaint files as deemed appropriate.
- The CHU that owns the complaint will be responsible for completing the assignments in the Assignments Page in the complaint file and ensure that all assignments are completed.
- Final Customer Information.
  - It is the responsibility of the CHU that complete information is transferred back to the customer. Information should include nature of the complaint as addressed by the customer, summary of the evaluation findings.
  - For J&J umbrella companies, complaint resolution must be reported back via Synergy resolution form or closure communication as indicated.
  - If customer communication is generated, then the communication should be scanned or saved and attached to the complaint file. However, CHU's may opt to save these communications hard copies in files per their local procedures. Complaint Handling Unit will need to document the complaint file when information has been physically archived in the Investigation Comments section.
- Final adverse event report if required.

5.4 Document & product retention

- Complaint files
  - Retention of complaint files are per local Document retention procedure

- Complaint files which are related to litigation will be retained until litigation is resolved

- Returned product complaint samples
  - Product complaint samples related to reportable adverse events shall be stored per records retentions schedule for complaint files. After retention period, they may be discarded/destroyed.
  - Returned complaint samples not related to reportable adverse events, may be discarded upon completion of investigation or per other time frame captured in local work instruction.
  - Refer to applicable local procedures for guidance information.

5.5 Complaint Tracking and Trending

- Product Complaint categories: Appropriate product complaint categories will be established for each device family.

- Establishment of Product complaint Categories / Codes
  - Product complaint categories are to be established as part of the design effort for the device.
  - Complaint codes should be linked to product design issues established via a FMEA or other risk assessment tool if appropriate. Complaint codes should be referenced to appropriate Global Defect Classifications if they exist.

    - Maintenance of product complaint categories / codes
    - Global process will be developed for the maintenance of complaint categories. This process to include how new categories are added to existing release products and also how complaint categories are "retired"

    - Complaint Escalation

      - Complaint files will be reviewed for criticality. Files deemed as potential PQIs, including all death related complaints and trends, will be escalated to management as appropriate. Each CHU is responsible for local work instruction(s), which describe specific complaint escalation procedures.
      - For potential PQI's complaints, upon complaint file opening, a communication (i.e a voicemail, or as appropriate) will be left to appropriate management indicating receipt of the complaint. A list of appropriate management for potential PQI complaint notifications will be maintained by respective CHU, as applicable.
      - Complaint File Owner (respective CHU) will be responsible for annotating the Investigation Comments that Management has been notified of Potential PQI. For Example, "Management Notified of Potential PQI".
      - A Remetrex assignment "Potential PQI Notification Assignment" will be generated by the Complaint File Owner to the PQI Process Owner or designee.
      - PQI Process Owner or designee will annotate Investigation Comments section as appropriate and close Remetrex assignment. Refer to PQI Procedure PR551-002 for relevant information.

- Local Tracking and Trending
- Individual designated CHU may report to local site management on complaints processed at individual sites.

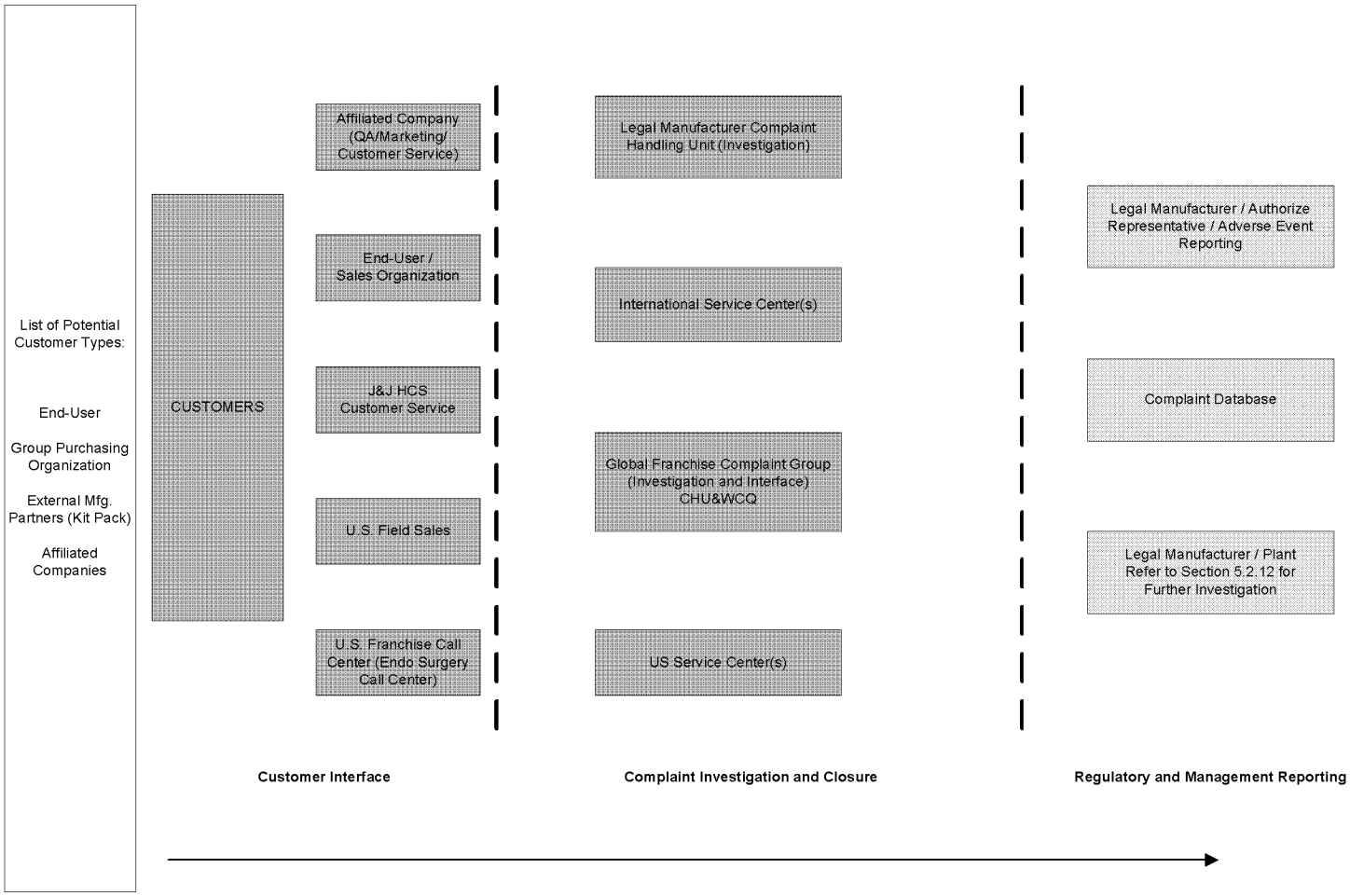
** //
- Global Tracking and Trending:
  - The Post Market Surveillance Group will conduct complaint reviews for each business unit on a monthly basis. The audience for these reviews should include representatives from WCQ, Marketing, Operations, Research & Development and Quality Assurance. In the absence of these attendees, an electronic copy of these reviews will be made available to these groups.
  - All actions and decisions of the monthly complaint reviews will be documented and maintained as a quality record, including attendees or designee names/roles. If the monthly review results in action driven items, the decision and rationale will be documented in meeting minutes. If an issue requires escalation, this will also be documented in meeting minutes and the issue will be escalated to the appropriate group.
  - General complaint data covering all products will be discussed at the monthly complaint reviews. At a minimum, a detailed review and discussion of the top five product families with the highest volume of reported events will be part of these reviews. Complaint data involving deaths will also be reviewed and discussed. Other complaint data may be included on an ad-hoc basis.
  - Tracking and trending of data will be performed following PR-0000368: Tracking and Trending of Quality Systems Data.

6 Appendices

Appendix Number	Appendix Title
I	General flow chart of global overview of complaint management process for ETHICON Franchise
II	Process flow chart for individual CHU activities
III	Minimum Information Requested as part of the complaint investigation
IV	Quality Conclusions for Complaint Investigation Review
V	Medical Assessment Conclusions for Complaint Investigation Review

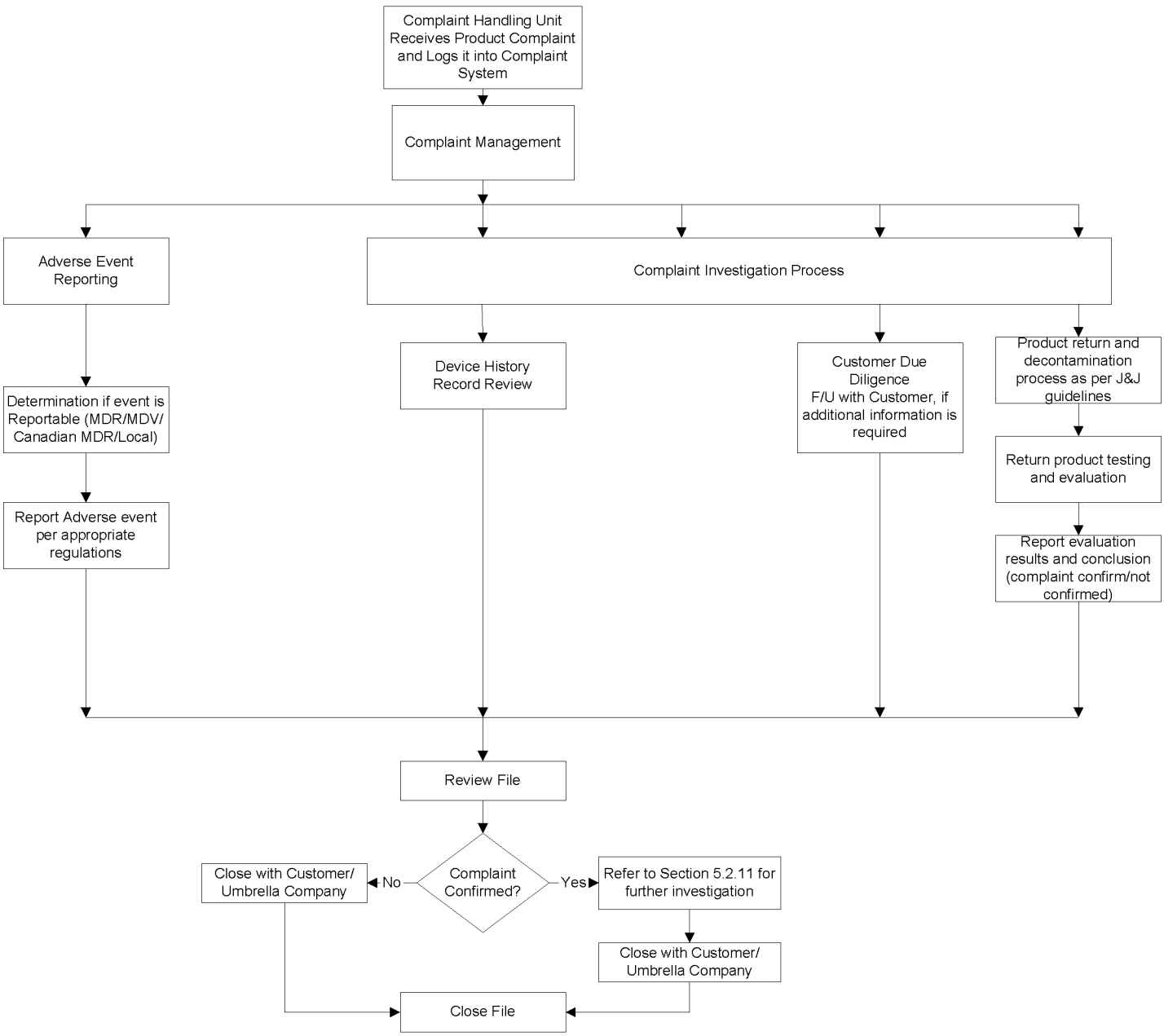
Appendix I

General Flow of Global Overview of Complaint Management Process for Ethicon Frachise



APPENDIX II

Product Complaint Process Flowchart for Individual CHU's



Appendix III

Minimum information requested as part of the complaint investigation:

- Reference Number(s) - Affiliate number, CHU number
- Affiliate Information, if applicable
- Sales rep name
- Sale rep contact information
- Date reported to rep
- Date rep reported to CHU
- Event date
- Customer Name
- Customer contact information
- Procedure name
- Procedure date
- Used for Diagnostic / Therapeutic (if applicable)
- Nature of complaint / Description of Event
- Physician or Hospital or Reporter contact information
- Patient information (if available)
- Event occurred Pre-Op / Intra-Op / Post Op
- Adverse Patient outcome No / Yes -description
- Medical Intervention taken
- Pre-existing medical condition (if available)
- Product being returned – Yes/No non-sterile or sterile
- Reusable device Y/N - device re-sterilized Y/N method if available
- Replacement required Y/N
- Customer follow up required (acknowledgment, phone call, visit, closure letter, detailed report of investigation etc..)
- Other Customer or Event or Product relevant information, as appropriate
- Product identification – product code, lot no., serial no.
- Did customer notify regulatory agency (FDA, Competent Authority) of event Y/N

Appendix IV

Quality Conclusions

1. **Device Met specifications**
The product met specifications per the batch record reviews conducted for the device.

2. **Cannot conclude that the device did not meet specifications**
It cannot be concluded that the product met specifications as no batch number was provided and a trending was performed.

3. **Device did not meet specifications.**
The product did not meet specifications per the batch record review.

Appendix V

Medical Assessment Conclusion Definitions

1. Device Caused Event

The normal performance/characteristics or structural/functional deficiency of a product (device) produced a serious injury/death to a device recipient/patient or a device user/operator.

2. Device Contributed to Event

The normal performance/characteristics or structural/functional deficiency of a product (device) served as a partial cause of a serious injury/death to a device recipient/patient or a device user/operator.

3. Device Potentially Contributed to Event

In the absence of direct clinical evidence, the normal performance/characteristics or structural/functional deficiency of a product (device) is deemed a potential contributor to a serious injury/death to a device recipient/patient or a device user/operator, based solely on the current medical and scientific knowledge.

4. Device Not Likely Related to Event

In the absence of direct clinical evidence, the normal performance/characteristics or structural/functional deficiency of a product (device) was deemed not likely to have connection with a serious injury/death to a device recipient/patient or a device user/operator, based on the current medical and scientific knowledge.

5. Device is Not Related to Event

Solid and legitimate clinical evidence indicated no connection between the normal performance/characteristics or structural/functional deficiency of a product (device) and a serious injury/death to a device recipient/patient or a device user/operator.

6. Not Enough Information to Draw a Conclusion

After demonstrating sufficient due diligence during complaint investigation, the available information is still not sufficient to support any of the five conclusions above.